Report of the Review and Implementation Committee for the Report of the Manitoba Pediatric Cardiac Surgery Inquest

May 2001

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Dedication

The Review and Implementation Committee dedicates this Report to the memory of the 12 infants who died in the pediatric cardiac surgery program at the Winnipeg Health Sciences Centre in 1994, and to their families who, despite having done nothing wrong, have suffered a tragic loss. It is our hope that your loss will protect future generations of children and their families, and that this Report will contribute to preventing similar events from ever occurring in the future.

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May 2001

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Acknowledgements

The Review and Implementation Committee (Review Committee) could not have understood the complicated issues involved and completed its work in a reasonable period of time without the support of many people.

The Review Committee wishes to begin by thanking the ten families who met with us to discuss the deaths of their children, the Inquest process and their assessments of the recommendations made by Judge Sinclair. We address the families directly in the text of our Report, but we wish to also thank them here for sharing their stories and providing us with insights which we could not obtain elsewhere. We realize the process of talking to strangers about these tragic and disturbing events was not easy. We hope that the families will accept the Dedication at the front of this Report as an expression of our sympathy and admiration for them. The list of the families whom we met is printed below.

The Review Committee benefited from the specialized knowledge and experience of a large Advisory Committee representing most of the leading institutions involved with the events which were under investigation during the Inquest process. We would like to thank our colleagues for their assessments of the recommendations in the Inquest Report, their advice on related matters, and the provision of additional material when it was requested. We can honestly say that all the individuals and institutions involved were accessible and helpful, despite the possibility that we would end up being critical of their actions. We were impressed by the willingness of the members of the Advisory Committee to be open and candid in the presence of professional colleagues from other institutions. The members of the Advisory Committee and other participants in the Review Committee process are listed in Appendix B.

The Review Committee met with a number of individuals and organizations and received written submissions from others. This material was valuable to the Committee because it offered either first-hand knowledge of the health care system and/or passionate advocacy of the necessity for change.

The Review Committee met a number of times with the Minister of Health, the Honourable Dave Chomiak, M.L.A., and the Acting Deputy Minister of Health, Ron Hikel. We wish to thank them for selecting us to undertake this challenging assignment, for their support throughout the past four months, and for respecting the independence of the Committee to allow it to reach its own judgements on the issues.

The Committee had the services of Guy Corriveau, a recent Masters Graduate in Public Administration, who located reference sources and prepared the select bibliography at the end of the Report. The Committee expresses its appreciation to Mr. Corriveau for his excellent work.

Lori Burrows of Manitoba Health supported the Committee in a very professional and dedicated manner. She coordinated the flow of paper and typed successive drafts of the Report. Her work was crucial in enabling the Committee to complete its task in a timely manner, and we express our sincere appreciation.

Last, but far from least, the Committee wishes to thank most sincerely Tom McCormack, Senior Policy Advisor in Manitoba Health, who provided both insightful advice on the issues, along with excellent administrative support. While serving as Secretary to the Committee, Mr. McCormack continued his regular departmental duties and juggled numerous assignments with exemplary professional knowledge, skills and commitment. Put quite simply, the Committee could not have done its work without him, and we wish to express our admiration and gratitude for his efforts.

Linde Feakes
Barbara Petkau
Walter Petkau
Danica Terziski
Sara Tena
Benedict Capilli
Donna Still
Shirley Still
Laurie Maguire
Barbara Maguire
Richard Shumila
Emily Ulimaumi
Mary Kay Pameolik
Sheena Goyal
Vipan Goyal
Charlotte Caribou
Morris Dell

Chapter 1

The Committee's Mandate and Operations

Introduction

Manitobans expect appropriate and effective health care for themselves and others. They want to be served by health care providers who are professionally competent on a continuing basis; are committed to the highest standards of quality care consistent with available resources; are responsive to and respectful of their patients and accept responsibility and accountability, both individually and collectively, for their behaviour and the outcomes of their activities. Most of the time Manitobans receive what they expect and they want.

Sometimes things go wrong. The work of this Committee was a response to an Inquest Report into the tragic deaths of 12 infants in the pediatric cardiac surgery program at the Health Sciences Centre in 1994. The overriding aim of the Inquest and of this Report was to provide recommendations for actions that would prevent a recurrence of such a tragedy and would contribute to the restoration of public trust and confidence in the institutions and participants involved, as well as in the health care system in general. In the course of doing its work over the past four months, this Committee has come to appreciate the magnitude of the challenges faced by Manitoba's health providers who work daily in the complicated, turbulent and uncertain environment of the health care system. All Manitobans want the complex, multi-dimensional and dynamic health care system to be many things: safe and high-quality, effective and efficient, accessible and responsive, coordinated and integrated, fair and ethical, and transparent and accountable.

Achieving these highly desirable values within a large, interdependent system which depends upon multiple institutions and highly specialized expertise and skills is an enormous challenge for all the stakeholders. It was not our task to develop a plan to reform the health care system in general. It would be presumptuous in the extreme to believe that we could acquire the knowledge and insights for such an exercise working part-time for four months. We also recognize the danger of generalizing from the experience of one medical program within one institution during one period of time. However, because the Inquest Report

made general, as well as specific, observations, findings and recommendations regarding Manitoba's health care system, we were inevitably drawn into wider ongoing debates.

TERMS OF REFERENCE OF THE REVIEW AND IMPLEMENTATION ADVISORY COMMITTEE

The Review and Implementation Advisory Committee (henceforth described simply as the Review Committee) was established in response to the publication of the 516 page *Report of the Manitoba Pediatric Cardiac Surgery Inquest: An Inquest Into 12 Deaths at the Winnipeg Health Sciences Centre in 1994*. The Inquest Report had been prepared by then Associate Chief Judge Murray Sinclair of the Provincial Court of Manitoba. Henceforth, the Inquest Report will be referred to as simply the Sinclair Report. The Sinclair Report was released on November 27, 2000 and the Review Committee was announced by the Honourable David Chomiak, Minister of Health, Government of Manitoba, on December 1, 2000.

The purpose of the Review Committee was to advise the Minister of Health and the Government of Manitoba on the appropriate follow-up actions on each of the Sinclair Report's findings and recommendations. More specifically, the terms of reference called for the Review Committee to:

- Complete a comprehensive review of the Report.
- Assess the recommendations in terms of:
  - What change has occurred since 1994 that addresses the recommendations;
  - What initiatives are currently underway that will address the recommendations;
  - What future actions should be taken to address the report's recommendations; and
  - What are the larger implications of the recommendations in terms of policy, legislation, programming, finances, structures and administrative processes?
- Provide regular updates on the progress of the Review and Implementation Advisory Committee to the Minister of Health.
- Advise the Minister/Government on the priority with which recommendations should be acted upon.
- Advise on the policy direction, program improvements, interprovincial implications and the financial impacts as the review of the Report progresses.
- Advise the Minister of Health on potential options for ongoing monitoring of the pediatric cardiac program.
- Advise the Minister of Health on the implications of the Report's recommendations for other pediatric programs in Manitoba.
- Produce an Implementation Report articulating actions undertaken, actions underway and proposed, including policy and program changes. The Report will also include appropriate time frames and recommendations for a monitoring program to ensure ongoing program quality.

- It is understood the Review and Implementation Advisory Committee will not be asked to comment on compensation to the families identified in the Sinclair Report.

The three members of the Review Committee appointed by the Minister of Health are Paul Thomas, Gail Bagnall and Helga Bryant. Brief biographies of the members of the Review Committee are provided in Appendix A of this report.

The Review Committee was given until March 31, 2001 to complete a comprehensive assessment of the findings and recommendations of the Sinclair Report. It was announced at the outset that the report to the Minister of Health from the Review Committee would be a public document. To ensure that the Review Committee completed its work in a timely manner and kept the Minister of Health apprised of its progress, provision was made for monthly updates to the Minister.

How the Committee Conducted Its Work

The Review Committee held its first meeting on November 27, 2000, the day of the release of the Sinclair Report. Due to the complex and multi-faceted nature of the recommendations from the Sinclair Report, the Review Committee established an advisory group consisting of representatives from many of the key stakeholder organizations within the Manitoba health care system. Not only did the availability of this expert group of advisors assist the Review Committee in assessing the recommendations of the Sinclair Report, it also allowed us to understand the interrelationships among various organizations and, hopefully, to provide an integrated response to the Sinclair Report's wide ranging recommendations.

Our advisory group consisted of one or more senior representatives from the following organizations:

- College of Physicians and Surgeons of Manitoba (CPSM)
- Manitoba Association of Registered Nurses (MARN)
- Health Sciences Centre (HSC)
- Winnipeg Regional Health Authority (WRHA)
- Office of the Chief Medical Examiner (OCME)
- Manitoba Health
- Manitoba Justice

The listing of participants from each of the institutions represented on the advisory group, as well as ohters who participated in the Review Committee process, is found in Appendix B. The Review Committee wishes to thank sincerely these individuals for their valuable contribution to our understanding of the issues arising from the Sinclair Report. We recognize that these were busy people with many other demands on their time in other parts of their professional lives, and we appreciate their generosity and commitment in sharing their experience, knowledge and insights with us.

The review process proceeded through meetings on several levels. At the first meeting of the Review Committee and the larger advisory group, agreement was obtained on a number of points.

First, it was agreed that the institutions represented on the advisory group would be free to act on the recommendations in the Sinclair Report that fell within their jurisdiction and which required immediate action. However, it was agreed that to enable the Review Committee to produce a coherent and coordinated plan for the Minister, it would be kept informed of the actions taken by the various institutions.

Second, it was agreed that the Review Committee and the advisory group would conduct their deliberations in private. Confidentiality was intended to promote frank and full discussions so that the Review Committee could obtain the benefit of understanding the range of perspectives on the Sinclair Report. Since it had been announced that the final report from the Review Committee would be a public document, the use of private meetings to debate possible recommendations was deemed to be acceptable.

Third, the Review Committee discussed and agreed upon the following criteria to be used to evaluate the findings and recommendations from the Sinclair Report.

CRITERIA FOR ASSESSING RECOMMENDATIONS:

- urgency/sensitivity of recommendations
- importance and scope of the impact
- timeliness/recent developments
- clarity of the recommendation
- soundness of the analysis/comparison to "best practices" elsewhere
- consistency of the recommendations with each other
- response of the stakeholders to the recommendations
- policy requirements/legislation
- program changes
- structural reforms
- administrative changes
- feasibility of recommendations in terms of available knowledge, costs, administrative requirements and political support
- the extent of agreement on recommendations within the Review Committee and the advisory group.

In finalizing its recommendations for this report, the Review Committee kept these evaluative criteria in mind.

In terms of working with the advisory group, the Review Committee adopted the following approach. At our initial meetings we asked each of the seven organizations to provide their initial assessment of the Sinclair Report, to indicate any relevant developments which had taken place between the conclusion of the Inquest and the appearance of the Report and any immediate actions they were contemplating based on the Sinclair Report. A series of meetings involving both the Review Committee and all members of the advisory group were held to discuss the findings and recommendations summarized in Chapter 10 of the Sinclair Report.

At the same time the individual organizations were asked to prepare a written submission analyzing the findings and recommendations for which they were primarily responsible based on four questions:

1. What developments, if any, have taken place within your organization which affect the recommendations made in the Sinclair Report?
2. What immediate steps, if any, has your organization taken in response to the Sinclair Report?
3. What is your assessment of the recommendations of the Sinclair Report?
4. What gaps, if any, were there in the Sinclair Report?

On the basis of the written submissions obtained from the organizations represented on the advisory group, the Review Committee drafted a series of additional questions. These questions served as the basis for a private meeting with representatives from each organization within their building. Typically, these meetings involved anywhere from four to 12 people and lasted two to three hours. This process enabled us to obtain a more in-depth understanding of the organizations. All the organizations did an excellent job in preparing additional material for the Review Committee.

The Review Committee wanted at the earliest possible stage to meet with the families of the 12 children who had died in 1994 in the pediatric cardiac surgery program at HSC. It was recognized that for a number of reasons, the families might not wish to meet with the Review Committee. We were eventually able to meet with one or more representatives from ten of the 12 families, in all cases with their legal counsel present. Issues of legal expenses and compensation for loss were deliberately excluded from the terms of reference of the Review Committee and this was made known to the families and their lawyers in advance of the meetings. The aims and outcomes of these meetings are discussed in a later section of this introductory chapter entitled "Our Message to the Families."

The Review Committee did not directly solicit input from organizations and individuals in the health care system or from the general public. The available time and resources did not permit an extensive consultation exercise. However, the committee was approached by a number of organizations and individuals, and we tried to meet with as many of them as possible. When it was not possible to meet interested parties, we encouraged them to provide us with a written submission outlining their concerns related to the Sinclair Report. Among the individuals and organizations whom we met or heard from in writing were other families whose children were involved with the pediatric cardiac surgery program, nurses who were working at HSC in 1994, an advocacy group promoting greater physician accountability and lawyers who were involved with the Inquest process.

Another source of background information used in the preparation of this report was a review of some of the vast literature on quality medical practice and the accountability of the health professions. The availability of the Internet and the use of a researcher on a short-term contract enabled the committee to obtain a significant amount of material on practices in other jurisdictions. We were particularly interested in developments elsewhere that raised issues comparable to those addressed in the Sinclair Report. This led us to the inquiry into the deaths of children in a pediatric surgery program in the Bristol Infirmary in England that took place in 1998. There was considerable public debate arising from the Bristol inquiry and significant policy, regulatory and institutional changes were introduced in response to it, and other damaging disclosures about the health care system in the United Kingdom. In using this and other comparative exam-

ples, we have tried to recognize differences among health care systems so that we do not recommend the transfer of features which do not fit appropriately within the context of Manitoba and Canada.

Readers should also note that we have not tried to document precisely the sources for points which are raised or the information that is presented. Instead, for most of the major topics covered in the report we have provided a list of reference sources that could be consulted for further information and guidance for the responsible decision-makers. These references are found at the end of this Report.

Finally, the Review Committee could not have completed its assessment of a lengthy and complicated report without the very professional, insightful and dedicated support of Tom McCormack, Senior Policy Advisor at Manitoba Health, who served as Secretary to the Committee. We express our appreciation more fully in the Acknowledgements section of this report, but we would be remiss if we did not also indicate here that the completion of a large and sensitive task would simply not have been possible without his valuable contribution. Among Tom McCormack's duties was the coordination of support from the professional and administration staff at Manitoba Health.

The Review Committee, especially the Chairperson, would also like to thank sincerely Lori Burrows of Manitoba Health for preparing successive drafts of the Report and coordinating the flow of paper produced during our proceedings that allowed us to complete our work in a timely manner. We are particularly grateful to Lori because the Committee's work was added to her regular duties.

THE SINCLAIR REPORT AND THE REVIEW COMMITTEE'S MANDATE

The Inquest Report from Judge Sinclair released on November 27, 2000 was the outcome of events that transpired in the pediatric surgery program at HSC in 1994. During 1994, 12 children died while undergoing, or shortly after having undergone, cardiac surgery. In February 1995, the HSC announced that it was suspending the pediatric surgery program. Shortly after this suspension, demands from the parents caused the Chief Medical Examiner for the Province of Manitoba to order an Inquest. The Inquest commenced its hearings in December 1995 and the final hearings were held in the fall of 1998. In total, more than 80 witnesses were heard over 285 days of testimony and nearly 50,000 pages of transcripts and thousands of documents were produced.

We mention these facts for two reasons that we elaborate upon in this section. First, the Review Committee was not appointed to duplicate the detailed inquiry into the events of 1994 that was conducted by Judge Sinclair. Second, more than six years have passed since those tragic events, and more than two years have passed since the Inquest concluded its hearings. For everyone concerned, especially the families, there has been a long period of waiting for actions to be taken and perhaps for closure to be obtained on these understandably emotional events.

We will begin this discussion with how we interpreted our mandate. The principal task of the Review Committee, as set forth in our Terms of Reference presented earlier, was to advise the Government of Manitoba, through the Minister of Health, on which recommendations in the Sinclair Report or other actions are required to prevent a recurrence of an abnormal number of deaths or other negative outcomes

in a pediatric cardiac surgery program should one be restarted in Manitoba or in other hish-risk surgical programs. Although we were asked at times, especially by lawyers representing the families, to revisit issues raised in the Inquest proceedings, we were obliged by the nature of our mandate and the time available not to review such issues in depth. For example, we made only limited, indirect use of the 50,000 pages of transcripts from the Inquest. Rather than focus on the past, we sought to identify institutional arrangements and procedures that would provide Manitobans with a stronger guarantee of competent, safe and ethical health care in the future. However, we still faced the challenge of evaluating the soundness of the analysis in the Sinclair Report as to why the negative events transpired at HSC in 1994 so that we could understand the connection between Judge Sinclair's findings and his recommendations.

The Sinclair Report contains 516 pages of detailed analysis. Given the scope of the issues investigated, their inherent complexity, the controversies surrounding them and the deeply sensitive nature of the events involved, the Sinclair Report is in our judgement a remarkably clear, readable, insightful and balanced report. Where we disagree with the recommendations, we do so respectfully, mainly on the basis of the different mandate we were given compared to the purpose of the Inquest. Judge Sinclair made it clear upon release of his Report that he did not wish to discuss his findings, either publicly or privately, on the grounds that he did not wish to influence potential legal proceedings that might occur and because after more than five years of living with the issues he wanted to return full-time to his judicial duties. The Review Committee respected his wishes, and did not try to contact him, but we recognize our debt to his valuable work.

Depending on how they are counted, the Sinclair Report made approximately 36 recommendations. Most of the recommendations represent responses to the events of 1994, but a significant number involve proposals for wider changes to Manitoba's health care system. In addition to the recommendations, the Sinclair Report contains numerous findings of fact. In its detailed examination of events, the Report offers many observations that did not lead directly to recommendations. Fortunately for the Review Committee, Judge Sinclair drew together his overall findings and linked them to particular recommendations in Chapter Ten of his Report. This format provided the Review Committee with a useful focal point for its discussions.

It was not the task of the Review Committee to discover what caused the unfortunate deaths of 12 children at HSC in 1994. Even after a lengthy inquest involving thousands of pages of evidence taken under oath, Judge Sinclair could not come to a definitive conclusion on exactly why things went wrong in the cardiac surgery program and whether all the deaths were avoidable through better medical management. In his judgement nine of the 12 deaths were preventable. In contrast, the Pediatric Death Review Committee of the Manitoba College of Physicians observed in its 1994 Annual report (released in 1996) that four of the deaths of children might have been prevented. These somewhat contradictory findings suggest that medical decision-making is not as precise and predictable as is popularly imagined. At page 501 of the Report, Judge Sinclair observes that:

> "Much of the time involved in the writing of this Report has been spent in determining what occurred, when and how. To a certain extent, there remains the question of why. To that there are no easy answers."

We agree there are no easy answers. We became aware in the course of our deliberations of the numerous institutions, procedures and rules that existed to promote the competent, safe and ethical delivery of

medical care and to hold individuals accountable for deficiencies in performance. Yet all these mechanisms seem to have failed, not only simultaneously but repeatedly.

Risk and death are unfortunate reality in difficult medical programs like pediatric cardiac surgery. Preventative and protective measures are all the more important in such programs as a way to minimize risk and harm, as well as to ensure learning from unfortunate incidents. When unforeseen events, accidents or errors occur, appropriate actions must be taken, including disciplinary actions. The central aim of the Review Committee became: reinforcing existing and finding new means to prevent medical errors; promoting a high standard of care; ensuring timely responses when problems are identified; and holding all the institutions and individuals accountable to patients, to one another and to society at large for their performance.

At the risk of oversimplifying what is a thorough analysis, there appear to be four central themes of the Sinclair Report:

- The treatment of the children and their parents during the tragic events of 1994.
- The individual and collective competence and behaviour of health professionals, such as: the clinical knowledge and technical skills of physicians; the role of nurses within surgical programs and hospitals; and the importance of teamwork and communication among health professionals.
- The organizational context in which surgery programs operate, including the structural arrangement for assigning responsibility/accountability, the procedures to promote informed/responsible decision-making, and the climate and culture of the institution which shape in large part how activity is conducted on a daily basis.
- The responsiveness and accountability of the institutions to the wider community, such as the information to which people are entitled, and how external monitoring by professional regulatory bodies, Manitoba Health, the Office of the Chief Medical Examiner, the Government of Manitoba and others takes place.

These four themes appear throughout this Report and we return to them in our closing chapter.

Many of Judge Sinclair's recommendations are presented in general terms and the practical requirements and complications involved with implementing these ideas were not discussed at great length in the Report. Part of the task of the Review Committee was to investigate the potential effectiveness of the recommendations as responses to the problems and concerns identified in the Sinclair Report. We also considered the consistency of the recommendations in terms of presenting a coherent, integrated approach. The feasibility of the recommendations in terms of available knowledge, technology, staffing, administrative capability and funding was also a consideration.

OUR MESSAGE TO THE FAMILIES

Judge Sinclair points out that the death of a child is in some sense more tragic and poignant than the death of an adult. As he observes, society expects children to outlive their parents and parents feel a strong duty to protect their children against harm. The Sinclair Report made clear that the parents who lost their

children in the HSC pediatric cardiac surgery program did nothing wrong and were entitled to a higher standard of care. In addition to the burden of the loss of their children, they were not treated by some of the authorities within a complicated and intimidating system with the responsiveness, respect and dignity they deserved. They have received the apologies from the various institutions involved but based upon our conversations with them, we conclude that what they most desire is speedy and effective action to ensure that such tragic events can never happen again.

The Review Committee was able to meet with representatives of ten of the 12 families, in all cases with their lawyer present. There were several aims behind these meetings. We wished to learn the reactions of the families to the Sinclair Report in terms of whether the findings corresponded to their experiences, how they assessed the recommendations and whether the Sinclair Report overlooked any matters they considered important. The meetings also allowed the Committee to obtain a better understanding and sensitivity to what the families had been through, something that could not be captured adequately in the printed record of an Inquest Report. It is understandable that the families approached our invitation to meet them with a mixture of impatience, skepticism and frustration. After all, they have been waiting a long time to learn how things would change as a result of their loss.

Being told that a follow-up review was now to be conducted might further discourage them that serious action would ever be taken to address their concerns. The various delays involved over the years, however unavoidable or avoidable they might have been, have prevented at least some of the families from achieving emotional and intellectual closure on this tragedy. Some will never come completely to terms with what happened to their children, their families and their lives.

We deeply appreciate their willingness to come forward to share their views with us. It was clearly a painful process for them and we are very grateful for the insights they provided. We could not have done our work without them.

The disruptions to the lives of the 12 families are far from over. At the time that the invitation was issued to meet with our Committee, there were at least three other forums where the families could potentially be asked to revisit the events of 1994. First, there is now an investigation underway under the auspices of the College of Physicians and Surgeons of Manitoba involving the conduct of a number of physicians who worked at HSC in 1994. If those investigations lead to an Inquiry Panel, there is a good chance that family members will be called as witnesses and such hearings are usually held in public. Secondly, families might sue for damages for a wrongful death under the *Manitoba Fatal Accidents Act*. Use of the courts to obtain compensation could be a lengthy and expensive process. Thirdly, Judge Sinclair observed in his report that an inquest cannot make findings of culpability and therefore he could not appropriately offer an opinion on compensation. On the matters of the legal expenses incurred by the families in participating in the inquest, Judge Sinclair recommended that they be reimbursed in full by the Government of Manitoba based upon a report by an independent fact finder. Dealings with the fact finder and the Government of Manitoba on issues of expenses and compensation could represent an additional stage in the process for the families.

Terms of reference for the Review Committee explicitly and rightly excluded issues of legal expenses and compensation. Those are matters not within our expertise and are more appropriately dealt with by government and the courts. Our point in the above discussion is simply that we recognize that the families have

faced, in addition to their emotional loss, significant legal and other expenses, and their patience with an already lengthy process is understandably wearing thin. To the families we wish to say directly that we understand, to the extent it is possible, their feelings. We appreciate the valuable advice they provided us, and that our recommendations regarding future actions are intended to achieve a goal we share with them, namely, ensuring that other families can always count on receiving competent, safe and ethical care.

The format that we have adopted for the presentation of our commentary and recommendations on the Sinclair Report is as follows. Our analysis follows the sequence of the findings and recommendations set out in Chapter Ten of the Sinclair Report. The Sinclair Report's recommendations are reprinted in full at the end of Chapter Eleven. At the end of the analysis contained in each chapter, we present a summary of all our recommendations contained therein. At the end of the full report, we present a complete summary of the recommendations made in all the chapters.

Before addressing the Sinclair Report's recommendations, Chapter Two of this Report briefly sets forth the institutional context and the multi-dimensional nature of the accountability requirements within a health care system which is complex, dispersed, interdependent and dynamic. Ensuring strengthened accountability is a central theme of all our recommendations.

Chapter 2

The Institutional Context and the Search for Accountability

Introduction

In this chapter, we wish to describe briefly the legal and institutional environment of the Manitoba health care system. The following discussion may appear to move away from the main concerns of the Sinclair Report and the implementation of its recommendations. However, it is necessary to understand the complexity of the health care system and how particular changes would fit into existing institutional arrangements and practices. In making final decisions on the recommendations in the Sinclair Report, the Minister of Health, the Government of Manitoba and all of the stakeholders in the health care system must debate and decide the extent to which the problems identified in one surgical program in one institution during one period of time should lead to system-wide changes, including new controls and monitoring arrangements.

For at least the past decade the Manitoba health care system has been required to cope with a rate, breadth, depth and intensity of change that is probably unprecedented. Health care has always been a technically complex and dynamic field of activity within society. However, advances in medical knowledge and technical capacities, trends and developments within society, changing economic and financial conditions and shifts in public opinion have all combined to make health care probably the most politically sensitive and controversial field of public policy. A sweeping health care reform movement has arisen in response to these pressures.

The institutions and individuals involved with Manitoba's health care system have been required to deal with increased public demands and expectations, mounting cost pressures and budgetary restraints, ongoing reviews and reorganizations at all levels, and successive waves of change, both planned and unplanned. The events investigated in the Sinclair Report took place during this era of rapid change. While other developments within the health system cannot be offered as an excuse for what went wrong in the pediatric cardiac surgery program, acknowledging the wider context is important to understanding how institutions, processes and individuals might have failed to perform as the system required them to.

A central theme of the health care reform movement has been an insistence upon greater transparency and accountability throughout the system. The need for better accountability was also a central message of the Sinclair Report. In fact, accountability has become one of the "buzz words" of the health care field during the past decade and its widespread use has often drained the concept of clear and consistent meaning. To create a framework for the following analysis, we will briefly discuss some of the key concepts involved.

THE DEFINITION OF ACCOUNTABILITY

By accountability, we are referring to the obligation of an institution or an individual to be answerable for the performance of responsibilities that have been assigned or negotiated and to be subject to sanctions for non-performance. Four components comprise an accountable relationship:

- the assignment or negotiation of responsibilities along with the provision of commensurate authority and resources to carry out those responsibilities;
- the duty on the part of the accountable institution or individual to answer for the performance of responsibilities, especially through the provision of valid reliable and timely information;
- the duty of the authorizing institution or individual to monitor the performance of the agents acting on their behalf and to insist on corrections to performance when it is deficient;
- the potential use of sanctions and rewards to promote responsible behaviour and to recognize inferior and superior performance.

Accountability processes can operate both within the boundaries of individual organizations as well as between separate organizations. There can be both an individual and collective approach to accountability.

Formal accountability along the lines described above should be distinguished from an informal, subjective sense of responsibility: a self-imposed duty to do what is right based on prevailing standards and/or individual's sense of moral and ethical obligation. The notion of professional responsibility plays a key role in the allocation of authority within the health care system. Given the extensive training and expert knowledge involved with the various health professions, they have been granted on the basis of trust considerable autonomy to license and to regulate their members. The model of the self-regulating profession presumes that individuals are committed to the highest professional standards and to meeting the needs of their clients. Ongoing educational processes, disciplinary procedures and codes of ethics are among the devices used by the self-regulating health professions to promote responsible behaviour. Formal accountability mechanisms can serve to galvanize and reinforce the professional sense of responsibility which society mainly relies on to ensure that health professionals act in the public interest.

Accountability should also be distinguished from "responsiveness," although the two concepts are clearly related. Responsiveness refers to the inclination and capacity of health institutions and health care providers to recognize and to reflect in their actions the needs and the wishes of the particular individuals they serve, as well as of society at large. Prior to the 1960s, responsiveness of the health care system was left largely to the professionals who operated the system, particularly the physicians. During the past four decades, there has been a mounting challenge to the trust-based autonomy of the medical profession. The

result has been a growing tension between, on the one hand, the traditional, prevailing ethos of professional autonomy and the hierarchical nature of the organizational arrangements in the health care field, and on the other hand, the emerging public demands for greater openness, participation, consent, responsiveness and accountability. The trends resulting from this tension have involved changes to the structures and processes of self-governing control by various health professionals; increased requirements for accountability and indirect public input through Ministers and departments of health; demands for and new requirements for accountability to the community at large; and most recently, a growing demand for direct public input into health policy and decision-making. The tensions arising from these trends are evident throughout the findings and recommendations of the Sinclair Report.

The Changing Nature of Health Care Accountability

The Sinclair Report describes a dynamic, complicated, multi-tiered, multi-dimensional health care system of numerous institutions and actors who engage in both collaboration and competition. Identifying who is responsible and accountable for what in such a complex system represents a real challenge. Traditional approaches to accountability in the public sector emphasize the importance of unified direction and control. However, the reality of Manitoba's health care system involves devolution of authority, shared responsibility and shared power. The following discussion seeks to illustrate why a linear, straight-line approach to accountability in the health field is unrealistic. The sources of accountability in the health field are numerous: constitutional, legal/professional, institutional, hierarchical and contractual. The result is multiple types of accountability, each of which has its own definitions, processes, dynamics and criteria of what it means to be accountable. It is understandable if health care providers are at times confused and frustrated by the numerous, not always consistent types of accountability requirements they now face. The following discussion reviews only some of the main forms of accountability within Manitoba's health system.

Political Accountability

First, there is the **political accountability** of the Minister of Health and the Government of Manitoba for the overall safety, effectiveness and responsiveness of the health care system. Political accountability arises from the principles of collective and individual ministerial responsibility which are central to cabinet-parliamentary government. The principles of ministerial responsibility derive from both public law and from unwritten constitutional conventions or well-established practices. The principles are intended to ensure the ultimate accountability of governments to the public they serve.

Collective ministerial responsibility refers to the requirement that governments maintain at all times the confidence of a majority of the elected Members of the Legislative Assembly serving in the Manitoba Legislature. Responsibility for the overall direction of government, including taxing, spending, legislation and program decisions, is concentrated in the hands of the Premier and the Cabinet, who in turn are required to explain and defend their actions and inactions before the Legislature. In theory governments can

be defeated at any time, but more realistically in practice the real sanctions for mistakes or abuses of authority by governments is the loss of office at the next election. The principle of Cabinet solidarity requires that individual ministers contribute to collective decision-making. Having made their arguments in the confidential meetings of Cabinet, they are obliged to support the government's position in public or resign in protest.

In addition to their contribution to Cabinet decision-making, individual ministers assume responsibility for the activities of the departments they lead. The statutes which bring departments into existence provide for the appointment of a minister to be in charge. While departments remain the most familiar and main type of organization for the delivery of public programs and services, governments have increasingly relied upon non-departmental bodies (crown corporations, agencies, boards, commissions, etc.) within the public sector and upon other organizations (whether not-for-profit or for-profit) in the private sector to perform such functions. The field of health care is a leading example of where the policy frameworks and the funding decisions come from government, but most of the actual program delivery takes place in non-departmental and private organizations.

These facts complicate the search for political accountability. In theory, a minister who fails to provide appropriate policy leadership and administrative direction for his/her department can be forced to resign if serious negative consequences result. Less clear is the extent of ministerial accountability for actions that take place in non-departmental bodies where there is not the same degree of continuous ministerial involvement and supervision as is presumed to occur within a department. In practice, whether or not an individual minister is forced to resign is largely left up to the Premier, who will decide the matter on the basis of whether on balance, the offending minister has become more of a liability than an asset to the government. Rather than accept the demands of opposition parties that a minister be fired, the more usual practice by Premiers is to reassign the minister to a less demanding, lower-profile portfolio when the next Cabinet shuffle is made.

Transposing these principles to the health care field reveals how confusing the political accountability picture becomes in practice. It is the government of the day who establishes the policy framework for health, determines the share of the provincial budget devoted to health compared to other program fields, allocates funds among the different components of the health care system, prescribes certain health care services that must be provided and conducts ongoing monitoring of the performance of the health care system. These activities involve both Cabinet and ministerial decision-making. Information and advice to support decisions comes from Manitoba Health and from outside organizations. There is also a process of negotiation with the federal government over policy, finances and administration of health care matters.

ACCOUNTABILITY AND REGIONAL HEALTH AUTHORITIES

The adoption of the *Regional Health Authorities Act* in April 1997 delegated authority to Regional Health Authorities (RHAs) to plan, manage, deliver, monitor and evaluate health services within their regions. RHAs also have input into the development of policy, plans and health care standards being developed at the provincial level. Prior to regionalization, the Minister and Manitoba Health had more direct dealings with the operational side of health care institutions and health programs than they do today. Now, the

RHAs, in the form of their governing boards and their executives, stand between the institutions on the front-line of health care delivery and the Minister of Health and his/her department. Even though there is a straight-line delegation of authority from the Minister to the RHAs, the enforcement of political accountability seems somewhat more complicated in practice under the new arrangement. In effect, another link has been added to the chain of accountability leading back to the Minister and the government. Where provincial leadership and involvement ends and the responsibility of the RHAs begins is not entirely clear in practice. It might appear that the Minister of Health has less control over the health system than in the past, but he/she has several important prerogatives.

Under the *RHA Act*, the Minister can issue directives to the RHAs to carry out certain actions. The Minister and the department are expected to plan the health system, set policy directions, provide funding, monitor performance and set health and managerial standards. While the government and the Minister continue in important ways to set the parameters for delegated decision-making by the RHAs, the exact nature of the working relationship between the two parties is not clear. According to a report (the Health Care Financial Management and Accountability Review) delivered to the Ministers of Health and Finance in April 2000, there is an initiative underway to clarify the relationships between the Minister and the RHAs. Efforts to develop separate as well as shared responsibility and accountability domains should proceed as expeditiously as possible. Without a clarification of the relationships between the Minister and the RHAs and of the accountability mechanisms that will be used, the achievement of political accountability becomes somewhat problematic. Confusion surrounding who is responsible for what can lead to "discretionary accountability" in which the Minister and others in the health care system find it convenient to be accountable when good news is being reported and prefer to avoid or minimize their accountability when there is bad news.

Ministerial Responsibility: The Debate

It is just such bad news, involving the tragic deaths of 12 children in the pediatric cardiac surgery, that precipitated the Inquest lead by Judge Sinclair and the appointment of the Review and Implementation Committee to assess his Report. Nothing was said in the Sinclair Report on the issue of whether and when the Minister of Health and his/her department knew about the problems with the pediatric cardiac surgery program at HSC. Our concern is not with reconstructing the past, but with clarifying the accountability framework for the future. Consistent with the principles of ministerial responsibility presented above, and given the usual dynamic of the political process, it is often impossible for a minister to completely deny responsibility for what happens within his/her portfolio of departmental and non-departmental responsibilities. Neither the opposition parties in the Legislature, the media, or the public will allow the Minister to avoid accountability for unwanted developments within the health system. The real issue is what should happen under the doctrine of ministerial responsibility when serious mistakes occur. There is controversy on this issue.

Two interpretations of ministerial responsibility have emerged over time: the traditional, "hard" version and the more contemporary "soft" version. Under the "hard" interpretation, ministers would normally be

expected to resign if they played a direct role in a decision that led to disastrous consequences or if they failed to deal with a serious problem that had been brought to their attention. In such circumstances, opposition parties usually call for the resignation of the Minister and often they are supported by media commentators. This dynamic contributes to the public's expectation that when tragic events (like the Westray Mine disaster or the tainted blood scandal) occur, someone who is supposedly in charge must pay a serious and visible price for their errors of commission or omission. That someone, many people think, should be the Minister.

Others recognize that the Minister is not actually in charge of activities on a daily basis. The Minister of Health steers the health care system by remote control. Authority, resources and control are delegated to a wide variety of interdependent institutions and individuals. To keep on top of what is happening throughout the system, the Minister relies on information and advice from others. Clearly, the Minister has a duty to be as well informed as possible given the numerous demands on his/her time. However, in practice only a tiny fraction of the thousands of decisions being made daily throughout the health care system will ever be brought to the attention of the Minister of Health. These facts lead to the "soft" version of ministerial responsibility which suggests that if a Minister had no direct involvement with a decision, no advance knowledge, and did not approve of what took place, he/she should not be expected to resign. In this interpretation, rather than loss of office, the real sanction behind ministerial responsibility becomes the potential embarrassment and loss of reputation that occurs when unforeseen and unwanted events take place. Ministers are still accountable in the sense that they are obliged to explain what went wrong and to indicate what corrective actions they have authorized to prevent a recurrence of a problem.

Both the hard "punitive" model of ministerial responsibility and the soft "remedial" model of ministerial responsibility will continue to be invoked in political debates, depending upon the circumstances. Apart from ministerial transgressions of a purely personal nature (conflicts of interest or moral misconduct, for example) reliance upon the "soft" remedial model seems preferable. This model recognizes that the Minister may be carrying out decisions reached in Cabinet, with which he or she might not be in full agreement. It also recognizes that many matters are beyond the Minister's direct knowledge and control. Moreover, given the complexity, uncertainty and the risks involved with the health care system, there will periodically be unforeseen and unwanted developments, even when human error, neglect or misconduct are not involved. Insisting upon ministerial resignations in all circumstances would only mean that relatively experienced ministers would be replaced by new, inexperienced ministers. Abandoning to others problems that appeared during your time in office hardly seems like an act of responsible political leadership.

Therefore, in the health care system, ministerial responsibility should be seen as a duty to explain and to correct problems when they arise. Also, a clearer delineation of where political responsibility ends and administrative accountability begins, along with more transparency regarding political involvement in decision-making, would ensure a clearer focus for accountability. Not all issues should involve accountability through the political process. There are a number of other forms of accountability that supplement and complement the processes of ministerial responsibility.

Financial Accountability

Financial accountability represents a second type of accountability. It involves a concern for the economy, efficiency, effectiveness and equity of health care spending. These concerns should motivate people involved with health care delivery at all levels, from the Minister of Health all the way out to the people on the front lines who interact directly with users of the health system. With health spending already representing nearly 38 per cent of the provincial budget, and with the health care system facing strong cost pressures on many fronts, the need for strict financial management and accountability seems self-evident. The April, 2000 report to the Ministers of Health and Finance entitled *Health Care Financial Management and Accountability Review* (the Webster Report) observed that to hold institutions and individuals accountable for performance they must be entrusted with sufficient authority and financial resources to fulfill their delegated responsibilities. It must be recognized that there is often a trade-off between the range, the standards and the quality of the care provided and the resources available. This is not to suggest that all health problems require the injection of new funds. Effective responses may require the reallocation of spending from one area of health to another, and there are undoubtedly ways to improve the efficiency of health spending.

Funds are transferred from Manitoba Health to the various health care institutions on both a global and designated program basis. In the past, health care facilities have overspent their budgets, claimed that original funding levels were inadequate, and Manitoba Health has felt obliged to cover their deficits. While health care planning is ideally done on a multi-year basis, funding is currently provided on an annual basis. The complexities and uncertainties of health care funding may be unavoidable in many ways but they nevertheless create a blurred picture of accountability, especially when problems of program delivery arise and the public is looking for someone to blame. The Minister and Manitoba Health must come to an understanding on the levels of funding necessary to deliver programs and the RHAs must accept responsibility to deliver safe, competent and efficient health care within agreed-upon fiscal limits.

Results-based Accountability

Results-based accountability represents a third, relatively new approach within governments. It reflects a shift away from process, input controls over spending and program operations towards a focus on "outputs" and "outcomes." Outputs involve the types and levels of programs and services being delivered, while "outcomes" involve the actual impacts of the programs and services on the segment of society being served. In the case of health care, there is a recent, but rapidly growing movement towards some form of performance measurement as a way to better track the progress of the health system and its constituent parts.

Ideally measurement approaches should be applied to both the clinical and managerial outputs and outcomes within the health system. There are, however, significant barriers to the development of comprehensive performance measure systems for health. The barriers are analytical and technical, financial, institutional and even political in nature. To illustrate the point, several brief observations can be made. Measuring the link between particular outputs (programs and services) and outcomes in the real world is exceedingly difficult. To adopt performance measures like those suggested at several points in the Sinclair Report, will

involve large investments in information technology and data generation and analysis. Not all health institutions will be organizationally ready in terms of the knowledge and skills of their staff and their internal cultures to adopt a decision-making approach that is based upon the most recent performance evidence.

Under regionalization, Manitoba Health should have dropped much of its operational and transactional role of processing claims from other institutions and assumed more of a planning, standards setting, monitoring and evaluation role. Too much overlap and confusion regarding the respective roles of Manitoba Health and the RHAs would make it impossible to hold the RHAs accountable for the achievement of their mandates within the limits of the resources entrusted to them. For Manitoba Health to move away from involvement with operational matters will require several things to happen. It will require the Minister and senior managers in Manitoba Health to accept the risks that come with granting the RHAs more autonomy. Making the Minister absolutely liable for everything that goes wrong in the health field creates a culture inside Manitoba Health that emphasizes "error-free" administration. Not only is it unrealistic to expect no errors or surprises, the resulting approaches to accountability are costly and impair learning.

As the Webster Report (pp 12–13) made clear, Manitoba Health currently lacks the organizational capacity to "steer" the health care system by "remote control" as the model of regionalization envisaged. As part of a contemplated reorganization, the department intends to develop its internal capability in terms of planning, standards setting, information management, monitoring and evaluation. There will be significant upfront costs involved with these changes, including training for managers and staff to equip them for their new roles. Similar investments will be needed at the RHA, hospital and other institutional levels of the health system. However, over the longer-term, as performance information is gathered on a regular basis and used to monitor the health care system, there will be less likelihood of troubled programs escaping timely reviews and a greater prospect that health spending will become more effective.

LEGAL AND PROFESSIONAL ACCOUNTABILITY

Legal/professional accountability represents a fourth type of accountability. This type of accountability reflects the deference that is paid to the specialized knowledge and skills of the various professions. In the health field, there are approximately twenty self-regulating health professions. Put simply, professional self-regulation involves the delegation, through statutes, of government regulatory functions to a quasi-public body (like the College of Physicians and Surgeons of Manitoba and the Manitoba Association of Registered Nurses) that is officially expected to prevent or to reduce both incompetence (lack of knowledge, skill or ability) and misconduct (criminal, quasi-criminal, unprofessional and unethical behaviour). Professional regulatory bodies promote competent, safe and ethical behaviour by regulating in a number of areas: setting educational standards, licensing or certification, defining and enforcing scopes of practice, overseeing competence, handling complaints, disciplining members and requiring remedial actions.

The process of professional self-regulation in the health field is too complex to be reviewed here. However, two points germane to the later discussion of the recommendations of the Sinclair Report need to be made. First, the legal accountability of health professionals operates not only through the statutory regulatory bodies. Those self-regulatory processes interact with other legal systems, such as the criminal justice system, common law (torts and trust), human rights law and employment law.

The second important point in terms of the subsequent discussion is the need to distinguish between the "policing" or disciplinary aspects of the self-regulation processes and the ongoing educational activities of the professional bodies in working with their members. The distinction can be seen in the complaints procedures used by the College of Physicians and Surgeons to deal with allegations of misconduct and the Standards Committees procedures which are intended to be educational. Of course, the two processes are meant to complement and reinforce one another. Within society at large and reflected in the political process, there seems to be a shift underway from concern for the discipline of the minority of health professionals who violate trust to a concern for the collective activity of each health profession as a whole.

Hierarchical Accountability within Hospitals

A fifth type of accountability occurs within the framework of the individual organizations which comprise the Manitoba health care system. Hierarchical accountability involves the setting of direction, the delegation of authority, the allocation of resources from boards and executives at the top of the organizational structure and the requirements for reporting by the units and individuals below who are responsible for supervising and conducting operational activities. Unity of direction and command, the delegation of authority that is commensurate with responsibility and a single-line, direct accountability from the bottom to the top of the organizational pyramid were traditionally seen as essential requirements for clear and effective hierarchical accountability. Lack of clear direction, diffusion of authority, ambiguity of command and multiple lines of accountability, it is often suggested, leads to confusion, conflicts, hesitancy and irresponsible behaviour.

Applying traditional principles of organizational design in a hospital setting (especially a large, multifunctional tertiary hospital like the Health Sciences Centre) involves a number of complications. First, hospitals have been described by the leading management theorist Henry Mintzberg as "professional bureaucracies." The phrase refers to the emphasis on specialization in the design of hospital structures and the importance of expert knowledge in determining which groups have influence in hospital decision-making. While there is a hierarchical administrative structure in hospitals, traditionally the medical staff have operated somewhat independently of this structure. It is often asserted that what defines a professional is precisely the fact that he or she is accountable to his or her peers. It is the professional body that sets the rules and defines what is satisfactory performance.

Professional specialization within hospitals also tends to make wider corporate accountability somewhat problematic. One of the central challenges in creating governance processes for hospitals is how to combine clinical autonomy with unified direction, control and accountability. Rather than being relatively homogeneous and unified as traditional organizational theory presumes, hospitals are heterogeneous, pluralistic, decentralized, interdependent and diffuse in their power structures. Any significant issue worth tackling is likely to involve a variety of functions and departments. Cross-functional problem-solving is a difficult process because of the tendency of professionals to insist on autonomy, the emergence of "turf battles" over programs and budgets, and the complexity of the coordination challenges involved.

MANITOBA'S LARGEST HOSPITAL: THE HEALTH SCIENCES CENTRE

The Health Sciences Centre (HSC) is a large, sprawling hospital complex that covers 12 city blocks in the inner city of Winnipeg. It is a tertiary hospital that receives patients, not only from its immediate catchment area, but also from other parts of southern Manitoba, the North and from other provinces. In 2000, HSC admitted 20,000 adults, over 5,000 children and over 4,000 newborns. HSC is also a teaching hospital, with most of its medical personnel holding positions in the Faculty of Medicine of the University of Manitoba. For such dual positions, both the hospital and the University have to approve appointments. The HSC employs approximately 5,000 full and part-time staff. It operates hundreds of programs and sub-programs in fourteen clinical divisions. In the present Child Health Division alone, there are nine separate, but related program management teams in existence, as well as an overall Child Health Program Management Team to coordinate and oversee the various programs.

These facts are significant because they present a challenge for the leadership of the institution in terms of providing unified direction, promoting coordination and coherence among wide-ranging activities, achieving sound management and promoting responsible and accountable behaviour at all levels. There is no single, simple structural solution to these challenges. At least as important as organizational design are the climate, culture and patterns of communication that prevail within the institution – matters that are addressed later in this report.

Prior to June 1, 1994 the HSC was organized along the lines of functional specialties in what was called a portfolio system. In other words, the hospital was organized on the basis of vertical "silos" of medicine, nursing, operations, finance, etc. whereas service delivery occurred horizontally across these silos. This structure was criticized because people working together in a medical unit or a ward often fell within different administrative lines of authority and accountability. Like many other hospitals, HSC moved away from this structure through the adoption of a program management model. Transition to this model took place over a number of years, including the period covered by the Inquest. This may explain in part Judge Sinclair's comments about the ambiguous and confusing authority and accountability relationships that he observed.

It is difficult to describe the program management model in a few words, but the following principles are at the heart of the model. Programs are intended to:

- be designed around patient needs;
- be provided by interdisciplinary teams that are empowered to make decisions and be accountable;
- deliver services with a focus on innovation, quality assurance, continuous improvement and effective resource utilization;
- identify and monitor indicators related to clinical outcomes and quality service; and
- collaborate with other programs and services.

Programs are defined by population group and/or disease or health problems. They involve an array of disciplines, skills, technologies and resources. Each program is given its own governing structure in the form of a program committee or council.

By June 1994 at HSC, the previously separate portfolios for medicine, nursing, operations, etc. were regrouped in clusters around clinical programs; cost centres were realigned and multidisciplinary program teams were appointed. The major clinical programs (Child Health, Women's Health, Mental Health and Adult Surgery) were assigned to three of the four Vice-Presidents. A further reorganization that took place in October 1994 reduced the number of Vice-Presidents at HSC from four to three, each of which would be responsible for major clinical programs. At this time, HSC authorities made the commitment that one Vice-President would always be a physician (Chief Medical Officer) and one would always be a nurse (Chief Nursing Officer). The most recent reorganization that took effect in January 2001 is reflected in Figure 1 (p. 22). It shows that the Chief Operating Officer at the HSC (Dr. John Horne) now reports to the Chief Executive Officer of the Winnipeg Regional Health Authority (Dr. Brian Postl) and through him to the Board of Directors of the WRHA. At the time of the Inquest, there was a 19-member Board of Directors for the HSC, but that body was dissolved in April, 1999 following the adoption of the regional health authority model. It will be noted from Figure 1 that each Vice-President has both medical (or clinical) components within their portfolio, as well as corporate services components. Figure 2 (p. 23) shows that the Vice-President and Chief Nursing Officer (Heather Crawford) has responsibility for the Children's Program Team that oversees the ongoing operation of the various components. The team meets weekly, with the Vice-President and Chief Nursing Officer attending approximately every third week. Within the Children's Health Program responsibility for pediatric surgery has been consolidated in the office of the Department Head for Pediatric Surgery, who is currently Dr. Nathan Wiseman. Reporting to Dr. Wiseman is the section head for Pediatric Cardiology, who is currently Dr. Rennie Soni.

There is no longer a pediatric cardiac surgery program at the HSC. Patients requiring surgery are referred out of province, as is discussed later in this report. There are, however, other pediatric cardiology procedures (eg., catherizations) performed at HSC and these are now part of an international quality assurance program. We present a discussion of the future of pediatric cardiac surgery at HSC later in this report when we discuss the proposed Western Canadian Children's Heart Network.

As mentioned earlier, hospitals like HSC are complex organizations operating with limited resources in a rapidly changing health care environment. The goals and benefits of the program management model have been extensively debated and documented elsewhere. The challenge is to develop an organizational structure that fosters positive relationships, collaboration and ongoing communication within and among multiple professional groups, between program teams and corporate services and with other internal and external stakeholders. Recent reorganizations at HSC have clarified and consolidated lines of responsibility and accountability. Of necessity, there remain significant areas of shared authority and collective accountability for activities and outcomes. Later in this report, we will make the recommendation that issues of internal accountability need to be approached as an integral component of the overall management processes within HSC through the promotion of a "culture of accountability."

In addition to structural arrangements designed to delineate responsibility and accountability, the HSC has always relied on a variety of procedures and reporting requirements to promote competent, safe, ethical and accountable behaviour by all health care providers. All of these devices existed at the time of the deaths in the pediatric cardiac surgery program, but despite a pattern of adverse outcomes the problems of the program were not addressed in a timely manner. For this one program at least, the array of monitoring procedures fell short of what was required. Since the various devices used by the HSC to ensure competent care are discussed at some length later in this report, they will simply be listed here to illustrate how competent and responsible behaviour is promoted.

Figure 1

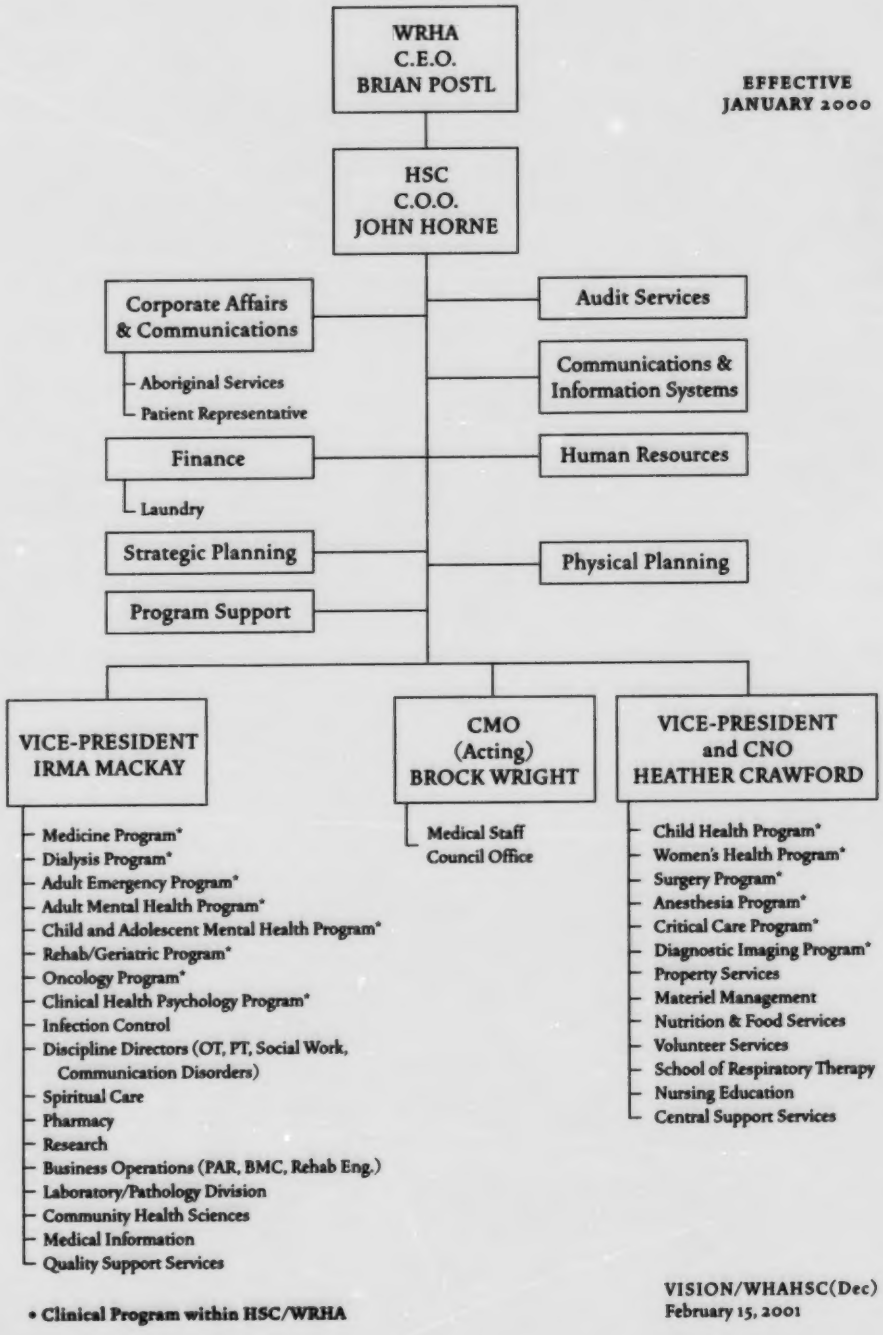
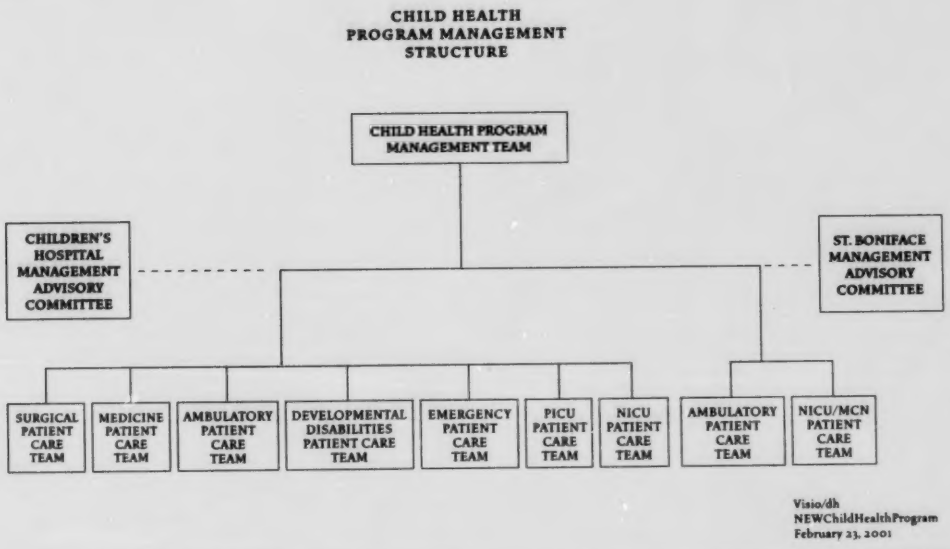

WRHA
C.E.O.
BRIAN POSTL
EFFECTIVE
JANUARY 2000
HSC
C.O.O.
JOHN HORNE
Corporate Affairs & Communications
Aboriginal Services
Patient Representative
Finance
Laundry
Strategic Planning
Program Support
Audit Services
Communications & Information Systems
Human Resources
Physical Planning
VICE-PRESIDENT
IRMA MACKAY
Medicine Program*
Dialysis Program*
Adult Emergency Program*
Adult Mental Health Program*
Child and Adolescent Mental Health Program*
Rehab/Geriatric Program*
Oncology Program*
Clinical Health Psychology Program*
Infection Control
Discipline Directors (OT, PT, Social Work, Communication Disorders)
Spiritual Care
Pharmacy
Research
Business Operations (PAR, BMC, Rehab Eng.)
Laboratory/Pathology Division
Community Health Sciences
Medical Information
Quality Support Services
CMO
(Acting)
BROCK WRIGHT
Medical Staff Council Office
VICE-PRESIDENT
and CNO
HEATHER CRAWFORD
Child Health Program*
Women's Health Program*
Surgery Program*
Anesthesia Program*
Critical Care Program*
Diagnostic Imaging Program*
Property Services
Materiel Management
Nutrition & Food Services
Volunteer Services
School of Respiratory Therapy
Nursing Education
Central Support Services
• Clinical Program within HSC/WRHA
VISION/WHAHSC(Dec)
February 15, 2001

Figure 2



Accountability as "Blaming" Versus Accountability as "Learning"

It should be noted that the various procedures involve both a retrospective, "fault-finding" blame-oriented approach to accountability with a prospective, educational and constructive approach to accountability. Of course, the better the preventative activities are, the less need there should be for attempts to determine liability and to apply sanctions of various kinds. The following are the leading examples of both approaches to accountability operating directly and indirectly at the HSC:

- the licensing of physicians, the granting of privileges at the hospital and the availability of the complaints process through the College of Physicians and Surgeons;
- the requirement for the periodic accreditation of the hospital and its programs, together with the conduct of program reviews;
- the use of quality assurance programs in connection with the accreditation process;
- on the basis of delegated authority from the College of Physicians and Surgeons the establishment of a series of Standards Committees for each medical program across the Winnipeg region to deal with deficiencies in performance through various kinds of remedial, educational activities;
- the use of rules and forms governing informed consent for medical procedures;
- the use of Critical Incident reporting forms and the establishment of Critical Case Review Committees to investigate situations where there was actual or potential harm to patients as a result of human error;

- the performance of autopsies by the Office of the Chief Medical Examiner in the case of hospital deaths falling within the terms of the *Fatality Inquiries Act*;
- the availability of a Patients' Representative Office to assist patients with the complicated structures, processes and information barriers.

The existence of these multiple processes to deal with problems may be necessary, but it is also no doubt confusing to patients who in times of distress want to know who they can talk to and how they can insist on satisfactory explanations of why things have gone wrong. We return to this theme later in the report.

"CUSTOMER" ACCOUNTABILITY

A final type of accountability might be labelled "customer" accountability. The phrase refers to the growing application of the language and concepts of consumerism to the provision of public services, including health care. The principles behind the consumer model include: access, choice, information, representation and redress. **Access** concerns can be seen in the insistence that health institutions become less confusing, impenetrable, bureaucratic mazes by offering integrated services, and that the criteria for providing services be brought into the open and debated. **Choice** refers to the opportunity for individuals to choose from alternative service providers and the availability of **information** to enable them to make informed choices. In the health care system, these principles are seen in the development of patients' bills of rights that provide a guarantee of a second opinion or a referral to another jurisdiction. They are also seen in the demands for hospital and physician "report cards" that document performance. **Representation** refers to the growing insistence that the views of the users of the health care system should be adequately represented to decision-makers at all levels in the system. This principle can be seen on the community level where there are demands for direct public input into decisions to close hospitals or to modify their programs. It can be seen in demands for strengthening consumer presence on the governing bodies of the health professions and for more transparency in the complaints processes dealing with professional misconduct. **Redress**, the final principle, refers to the need for mechanisms to settle grievances quickly, simply and fairly. It is seen in calls for the adoption of "whistle blowing" laws to protect health care providers from reprisal if they disclose illegal, unethical and incompetent conduct within the health care system. It is seen in the adoption of ombudsman-like functions within health institutions to deal with patient complaints of action or inaction.

The Sinclair Report reflects the emergence of these new ideas respecting public participation, consent and community-focused accountability. At this stage of their development, the emerging mechanisms for greater public input probably should be described as ways to promote better informed users of health care services, greater responsiveness throughout the health care system to community concerns and increased transparency surrounding the operation of the system. There are not as yet formal mechanisms for citizens to hold health providers accountable, but all the decision-makers in the health care system are facing better-informed and more demanding consumers of health services.

Concluding Thoughts

Several concluding points can be drawn from the preceding discussion of accountability. First, there are clearly a number of different types of accountability and approaches to enforcement operating within the health care system today. As new clinical problems and management issues have appeared, new accountability mechanisms have been added as supplements to, rather than replacements for existing accountability principles. Given the existence of several sources of authority and of diverse expectations, a multi-method approach to accountability seems appropriate. However, the emergence of multiple types of accountability means that health care providers will at times face cross-pressures and conflicting accountability requirements. Accountability is best understood as a dynamic process, rather than as a problem that is resolved once-and-forever. Institutions in the health care field need to formulate a broad approach to accountability that goes beyond simply compliance with legal, financial, hierarchical and contractual rules and procedures. Certainly the public no longer sees accountability in strictly legal and organizational terms. For them accountability is also a professional and moral construct that results when health providers put patients' needs first and are committed to provide competent, safe, quality and ethical health care within the limits of available resources.

Chapter 3

Recruitment, Selection and Retention of Medical Staff

Introduction

The Sinclair Report concluded that the loss and failure to replace physicians and surgeons at the Variety Children's Heart Centre during the years 1992 and 1993 were contributing factors to the deaths of 12 infants in the pediatric cardiac surgery program during 1994. Recruitment and selection procedures to hire replacement medical staff were described as flawed.

In response to these findings the Sinclair Report recommends a hiring process that ensures the best possible candidate is selected. The Report goes on to describe some of the key principles of a process that would ensure this occurs.

The Review Committee agrees that the recruitment and selection process should have as its primary aim the hiring of the best available candidate. Sound procedure can help to ensure that this occurs, and the recommendations of the Sinclair Report set forth some principles clearly important to such a process. However, our investigations and discussions with the relevant authorities suggest that implementing the general principles is easier said than done.

Hiring the Best Surgeon

Let us begin with the principle that the aim is to hire the best possible candidate. For many medical specialties, including high-risk surgical fields, attracting the top talent to Manitoba can be difficult. This was seen in the history of the pediatric cardiac surgery program at HSC. From the start of the program in the early 1950's, there was a shortage of surgeons, recruitment was difficult, the program was suspended during some periods, patients were regularly referred out of province and the success rate of surgeries performed at HSC was mixed at best (Sinclair Report, p. 103). Apart from other constraints, the relatively small population base of Manitoba makes it questionable whether a complete pediatric surgical program can be sus-

tained because surgeons are not presented with a sufficient number of cases to refine and maintain their surgical skills. A small number of pediatric surgeries also meant that pediatric anesthetists and pediatric/neonatal intensive care nurses did not have sufficient work to gain experience and to maintain their skills. Top-flight surgeons want to work where they can use their knowledge and skills to the full extent and work with surgical teams that are capable of high caliber of work. In summary we believe that it is simply not possible for Manitoba to create the conditions necessary for a full pediatric cardiac surgery program that can deliver high-quality care on a continuing basis. The alternative is for Manitoba to participate in the Western Pediatric Cardiac Network, a proposal which is endorsed in Chapter Nine of this Report.

TIMELY RECRUITMENT

The Sinclair Report called for a timely process for the recruitment and selection of physicians and surgeons. Officials we spoke to in several institutions said that the hiring process remains cumbersome and time consuming, with approvals needed on several levels. No fewer than six institutions potentially play a role in finding a new physician for a new medical program or replacing a physician who has left an existing program. The six organizations are: HSC (the relevant medical staff and the executive), the Faculty of Medicine at the University of Manitoba, the WRHA, the Minister and the Department of Health, the Treasury Board sub-committee of Cabinet of the Government of Manitoba, and the College of Physicians and Surgeons of Manitoba. Many of the hospital's senior medical staff also hold appointments in the Faculty of Medicine. Both the hospital and the University have to approve such appointments. Physician hiring has to some extent been centralized at the regional level of the WRHA working with the Physician Resource Planning Division of Manitoba Health. Under favourable circumstances the process of recruitment and selection can operate reasonably expeditiously, but it can present obstacles when there is a need to make a timely offer to a promising candidate.

ADEQUATE NOTICE BY DEPARTING PHYSICIANS

The Sinclair Report recommends that physicians and surgeons be required to give adequate notice before leaving a position in a hospital in order to allow adequate time for a replacement to be found. The principle is a good one, applying it in the real world is difficult, especially during the current period when competition for physician services has intensified. Physicians are hired under a variety of arrangements, including different remuneration models. Those who work on a fee-for-service basis will be reluctant to give early notice of their planned departure because of the impact on their patient populations and income. In some hospitals, doctors are hired on contracts with provisions respecting notice and penalties for early departure included. However, very few physicians are on contract. The examination of alternative employment and remuneration models is an area which could be usefully examined by the relevant personnel from Manitoba Health and the Regional Health Authorities of Manitoba. Adequate notice of departure should be stated in the letter of appointment of a physician and it should be emphasized that any breach of the notice provision would be included in letters of reference for positions elsewhere.

The Use of Search Committees and Recruitment Specialists

The Sinclair Report recommended that all recruitment should be done through a formal search committee, which included the head of the medical department and other relevant health personnel, including nurses. Improvements have been made to the recruitment process at HSC with formal search committees routinely being used. Consistent with the team approach which is intended to operate in the Program Management model at HSC, nurses and other health personnel are increasingly providing input into clinical job descriptions. Members of a surgical team must have the opportunity to meet candidates.

The Sinclair Report recommended that hospitals employ or contract with professional recruiters to assist committees, especially when hiring in high-demand specialties. The HSC has used personnel agencies when required in the past. With the WRHA playing a coordinating role in the recruitment process, it is becoming a repository of knowledge about the medical marketplace and what factors will attract physicians to Manitoba. No matter what formal recruitment procedures are put in place, approaches to former medical students from Manitoba and contacts through professional colleagues will remain an important source for recruitment.

Observing Surgeons At Work

The Sinclair Report recommends that surgeons should be observed in action; this is not always possible. Recruitment processes at HSC include reference checks prior to granting hospital privileges. Reference questionnaires include questions about clinical knowledge and competence, as well as personal behaviour traits, including the ability to work with others. Spontaneous interviews with a candidate's colleagues are a way to supplement formal reference checks. We were told that when one of HSC's pediatric cardiac surgeons was hired away, the entire surgical team from a U.S. hospital travelled to Winnipeg to observe him conducting surgery; this entails a significant investment of time and money. If a surgical candidate is unknown, the department head might travel to another location to observe her or him at work. HSC authorities inform us that newly hired surgeons not known to medical directors are observed during a probationary period. Having junior surgeons "shadow" their senior colleagues and establishing "mentoring relationships" are other ways to allow less experienced surgeons to refine their knowledge and skills with reduced risks to patients.

Teamwork as a Selection Criterion

The Sinclair Report recommended that the ability to work in a team context be an important criterion in the hiring process. A team philosophy could be determined through the formal reference questionnaire and the informal, "spontaneous" interviews with the colleagues of a candidate. Interviews with candidates and meetings with existing team members would provide other opportunities to gauge how candidates will adapt to the program management model which involves multidisciplinary teams focused on quality patient care.

There is a tension among the recommendations on recruitment and selection. The process is meant to be timely so that good candidates are not lost and there is less disruption to programs. On the other hand, using multidisciplinary search committees, recruitment agencies, visits to observe candidates and both formal and informal references will all take time. This tension suggests the need for advanced planning, early contact with prospective candidates, and requests for references as early as possible in the hiring process.

FEE SCHEDULES FOR SURGEONS

The Sinclair Report observed that one of the factors, that encouraged pediatric surgeons to leave Manitoba, was the lower fee schedule for pediatric cardiac surgery compared to similar surgeries performed on adults. Pediatric cardiac surgeons performed fewer, but more complex procedures than their adult counterparts, but derived less income and risked the atrophy of their skills due to a less than optimal number of cases. There have been no pediatric cardiac surgeries conducted in Manitoba since 1994 so there has been no need to revise the fee structure. Fee schedules are negotiated between the Manitoba Medical Association and Manitoba Health. In the past, Manitoba Health has focused on negotiating a global budget for physician remuneration and left the allocation of available funds among the various types of physicians up to the MMA. If Manitoba Health is to play a stronger role of strategic direction setting within the health care system, as we recommend in Chapter 10, it cannot be indifferent to variances in fee schedules among the specialties. Even if pediatric cardiac surgery on a stand-alone basis were never re-introduced in Manitoba, there are other specialized surgical procedures that Manitoba Health might wish to ensure are adequately supported in financial terms.

THE LEARNING CURVE AND STAFFING NEW PROGRAMS

The Sinclair Report offers very disturbing observations about the acceptance by the two department heads responsible for pediatric cardiac surgery in 1994 of the concept of a "learning curve" when new programs and new surgeons were being introduced into the HSC facility. Judge Sinclair wrote that "there should be no allowance for a learning curve where patient safety is concerned or when analyzing results of surgery." (Sinclair Report, p. 473). He observed that there was not a carefully planned start-up of the pediatric cardiac surgery program in 1994. Initial patient selection included cases that exceeded the capabilities of the surgeon and the team, and the program was not adequately monitored to detect and to correct problems.

On the basis of these and other findings, the Sinclair Report recommends that the HSC develop "protocols" for providing orientation and support to all new staff. The Review Committee believes that all health care facilities in the province should have mandatory orientation policies and programs, if they do not do so already. HSC has an Employee Orientation policy intended to integrate new employees and medical/nursing students into the HSC and into their respective departments and programs. Orientation for new staff occurs at the corporate, departmental and job specific level. Since physicians are not employees of the hospital, they are not included within the scope of this corporate policy. Orientation for physicians is depart-

mental in origin and varies significantly in terms of length, depth and type of material covered. HSC authorities acknowledge that some physicians receive no formal orientation and that others receive only the most cursory introduction to hospital policies, procedures, facilities, etc. Attendance at more formal, in-depth orientation programs would represent a loss of time and income for physicians and therefore they will resist having attendance made mandatory.

HSC is proposing a number of responses to the Sinclair Report's recommendations on staff orientation. It proposes to:

- survey current orientation practices for new physicians, residents, float pool staff and those returning from leave;
- review the current Human Resources Orientation policy to include physicians and surgeons;
- identify a mentoring role for medical program heads and section heads to support new physicians and ensure that time is available for this important function;
- ensure that physician orientation is as comprehensive as orientation for all hospital employees and include meetings with the Managers of Patient Care and the staff of the relevant patient care units;
- require each program/unit to have a written manual for new staff; and
- identify reporting and accountability relationships as part of the orientation for new staff, including for physicians.

At this point, these are proposals for action within HSC. The Review Committee congratulates HSC authorities for developing these reforms. However, as the old saying goes, "the proof will be in the pudding." The HSC should set a timetable for the implementation of the new orientation procedures. It should develop criteria for evaluation as a basis for reviewing the success of the new orientation program and it should set a date in the future for the completion of a systematic evaluation of how the program is performing. The evaluation study should be submitted to the Executive of the HSC. The Review Committee recognizes that there will be funding requirements for a revised, more inclusive orientation policy at HSC and recommends that there be discussions held with the WRHA about financial support for this important activity.

The Sinclair Report's other recommendations dealing with staffing were written in the context of the possible recommencement of the pediatric cardiac surgery program. The Review Committee recommends elsewhere in this Report that for the foreseeable future, a stand-alone pediatric cardiac surgery program should not be restarted in the Province. The evidence suggests strongly that a pediatric cardiac surgery program for Manitoba alone would not perform enough operations to allow the surgeons and other team members the opportunity to establish and maintain their skills at a high enough level to ensure competent and safe care within the parameters of acceptable risk.

The issue of appropriate staffing levels involves finding a balance between sufficient work for surgical teams to maintain skills versus overwork, fatigue and an increased risk of errors. The HSC has been working in a constrained resource environment for some time and there is a need to review staffing levels for all programs.

The Department of Pathology received special attention in the Sinclair Report. The concern was that a shortage of pathologists, especially individuals who specialized in pediatric pathology, had caused a delay

in the production of autopsy reports and a delay, therefore, in the detection of problems within the pediatric cardiac surgery program. The Review Committee comments on the death review process in our Chapter on the Office of the Chief Medical Examiner. Here, we wish to indicate that the shortage of pathologists persists. HSC authorities informed us that pathologists were handling 500 adult cases per pathologist per year, with approximately 150–200 pediatric autopsies also completed annually. The National Association of Medical Examiners considers more than 250 autopsies per year to be excessive. In addition to their medical-legal work on autopsies, pathologists perform a number of other responsibilities which actually take up more of their time. There are currently vacancies in the Department of Pathology at HSC and requests have been made to the appropriate authorities for new hirings. There is currently a national shortage of pathologists and remuneration levels in Manitoba need to be competitive.

In the case of anaesthetists, the problem during 1994 was not a shortage but a surplus of pediatric anaesthetists. At the time there were six to seven qualified anaesthetists and there were not enough pediatric cardiac operations to allow them to maintain their skills. As well, there was lack of continuity in the surgical team so that a familiar and trusting relationship between the surgeon and the anaesthetist was difficult to develop. Given the size of Manitoba's population and the likely number of pediatric cardiac surgeries to be conducted annually, there would continue to be inadequate opportunity for pediatric anaesthetists to refine and maintain their skills were a stand-alone program restarted at HSC. Therefore, the Review Committee is recommending in Chapter Nine that Manitoba participate in the Western Canadian Children's Heart Network.

RECOMMENDATIONS

The Review Committee recommends that steps be taken to expedite and better coordinate the physician recruitment and selection process among the organizations involved so that promising candidates are not lost.

The Review Committee recommends that contracts and letters of appointment of physicians should require a notice period for departures and that any breach of this requirement be included in letters of reference for positions elsewhere.

The Review Committee recommends that formal search committees be used for all hospital hirings. Such search committees should be multidisciplinary including physicians, nurses and other relevant health personnel.

The Review Committee recommends that a number of strategies be used in the recruitment and selection process to determine the willingness and demonstrated capacity of physicians and surgeons to work in a team context.

The Review Committee considers the proposal to observe all surgical candidates at work to be impractical in terms of time and expense. The Review Committee recommends that "junior" surgeons "shadow" their senior colleagues and that formal mentoring relationships be developed.

The Review Committee recommends that Manitoba Health identify anomalies in the fee schedules for physicians and surgeons that do not support provincial health priorities and seek approval for a bargaining strategy to correct those anomalies in advance of fee negotiations with the Manitoba Medical Association.

The Review Committee recommends that all health care institutions in the Province have written orientation policies and programs, and that participation in such programs be mandatory for all new personnel, including physicians.

The Review Committee recommends that Manitoba Health and the WRHA review the staffing levels for pathologists at HSC in light of the issue of timely autopsy reports raised in the Sinclair Report. This recommendation must be acted upon in conjunction with the recommendation in Chapter Seven on possible changes to the death review process conducted by the OCME.

Chapter 4

The Health Sciences Centre: Structure, Leadership, Culture and Communication

Introduction

The Health Sciences Centre is the main institution under scrutiny in the Sinclair Report. A number of features of the institution are discussed and become the focus for recommendations. Not surprisingly, in the dynamic environment of the Manitoba health system, many things have changed at HSC since the Inquest began in 1995 and even since the hearings were concluded in the Fall of 1998. In response to the release of the Sinclair Report on November 27, 2000, further changes were introduced or are under consideration at HSC. In this section, we review and assess the Sinclair Report's recommendations as they pertain to an ever-changing HSC. We see the four components of structure, leadership, culture and communication as key factors in the change process.

Structure and Accountability

Over the last several decades, Canadian hospitals have experimented with a number of alternative organizational designs – functional, divisional, matrix, program and various hybrids of these models. During the early 1990s, the HSC was embarking on a major reorganization involving a transition from a functional model to a program model. At the same time, the institution was facing deep budgetary cutbacks which occupied an enormous amount of the time and energies of the leadership within the institution. This was the context that Judge Sinclair encountered when he began his investigation early in 1995, which may explain in part why he was critical of a lack of clear lines of authority and accountability. Confusion over who had responsibility for addressing problems within the pediatric cardiac surgery program is blamed for delaying institutional responses. Complexity, interdependence and flux continue to characterize the structural arrangements at HSC.

In 1994, the HSC was beginning the transition to a program management (PM) structure. There were a number of reasons for moving away from the existing functional model towards a PM approach to:

- make patient care the focus of all institutional efforts;
- improve patient care by creating multidisciplinary teams at the unit level;
- involve physicians more in the management of clinical programs;
- allow for a more results-oriented approach to the management of clinical programs;
- control costs more effectively; and
- develop better linkages with community services.

During the 1980s, the PM model became the preferred approach of many large hospitals. Some Canadian hospitals have moved more completely than others to a structure that revolves completely around programs, including in some cases the full integration of clinical and functional services along program lines. The criteria for designating programs differ depending on the particular organization.

PROGRAM MANAGEMENT MODEL

Structural reform is not a panacea to cure what ails organizations. Reorganizations are often oversold and end up delivering far less than was promised. Structural change is not a "free lunch"; there are costs as well as benefits involved with redesigning organizations, especially if redesign happens too frequently. Introduction of a major structural reform like the adoption of a PM model is likely to encounter resistance for a number of possible reasons:

- seen as a threat to physician authority and autonomy;
- loss of areas of authority for existing departments;
- loss of control over resources;
- reservations about collaborating with other professionals, including reporting to a program manager who is not a member of your professional group;
- concerns about job security;
- lack of adequate consultation, with the result that the changes are not seen as legitimate; and
- the fatigue and frustration factor of undergoing yet another change.

We do not know the extent to which these concerns were a source of tension in HSC during the move towards the PM model. Success in applying that model depends to a great extent on the effectiveness of the relationships and interactions among the various professional groups involved.

The transition to the PM model at HSC has involved a number of reorganizations:

- In June 1994, the previously separate portfolios for medicine, nursing, allied health disciplines and support staff were regrouped on a clinical program basis, with multidisciplinary program teams empowered to operate and be held accountable for those programs.

- In October 1995, there was a reduction from four to three Vice-Presidents, each of which had responsibility for one or more major clinical program.
- In April 1999, the creation of the Winnipeg Regional Health Authority and the disappearance of the HSC Board of Directors was accompanied by the replacement of the President of HSC with a Chief Operating Officer, who then reported to the Chief Executive Officer of the WRHA. Also, at this time the HSC reduced from three to two Vice Presidents.
- The current organization chart for HSC, which became effective in January 2000 is shown as Figure 1 (p. 22). It displays the portfolio of responsibilities for the two Vice Presidents. Asterisks opposite the activities within those portfolios designate the current fourteen major clinical programs within the joint HSC/WRHA Clinical Program Management Structure. Within each of the fourteen clinical programs, there are many sub-programs and services.

As confusing as the above account might be to readers, it represents only the highlights of the main structural changes that have taken place in senior management at HSC. Simultaneously, a number of significant changes have been occurring in the middle and lower levels of the organization during the past decade. It would not be surprising, therefore, if many HSC employees were confused about the lines of authority and communication within the institution.

Communications about the structural and personnel changes has undoubtedly taken place, but more could be done to ensure that all HSC staff are aware of the revised lines of responsibility. It should be part of the job description of managers at all levels throughout the organization to ensure that new and continuing employees are aware of changes through orientation and reorientation activity and the development of devices like "accountability maps" which trace the lines of reporting back to the Chief Operating Officer and the WRHA Board.

Child Health Program Management Team

Some additional appreciation of the complexity of the structures, processes and relationships within HSC is gained by an examination of the Child Health Program Management Team. Figure 2 (p. 23) illustrates the nine program teams which operate under the umbrella of the overall team.

The Sinclair Report was critical of the diffusion of authority and accountability for pediatric cardiac surgery between the Head of Surgery and the Head of Pediatrics. Even before the Sinclair Report was released, HSC had made a number of changes to its structure to address this concern:

- it had appointed a Deputy Head, Department of Surgery, Pediatrics (Dr. Nathan Wiseman) with authority over all pediatric surgery;
- it had recruited a section head of Pediatric Cardiology (Dr. Reeni Soni);
- it had established the five-person Child Health Program Management Committee, which includes the Deputy Head, Pediatric Surgery;
- the Vice-President and Chief Nursing Officer, whose portfolio includes Child Health, attends meetings of the Child Health Program Management Committee on a periodic basis and meets regularly with members of the program team;

- the Child Health Program Committee has established a multidisciplinary critical case review committee;
- pediatric cardiac surgery has not been conducted at HSC since 1994, but the institution has participated in the development of the proposal for the Western Canadian Children's Heart Network.

The Review Committee acknowledges that valuable progress has been made in consolidating and clarifying authority and accountability relationships within the Child Health Program field at HSC.

There will always be complicating factors that make the precise, straight-line assignment of authority and accountability somewhat problematic in a complicated, multi-functional organization like HSC. Clinical and administrative decision-making must be integrated. There is the fact of interdependence and the need for collaboration, both horizontally across divisions and vertically in terms of decision-making on different levels within particular divisions. The use of multidisciplinary teams requires shared leadership, collective effort, the empowerment and involvement of individuals and the integration of perspectives, skills and experiences. Good teamwork requires agreement on performance goals and the willingness of team members to hold themselves mutually accountable for results. The most successful teamwork is founded on a basis of mutual respect and trust.

To achieve the benefits of teamwork while maintaining accountability, there are a number of requirements:

- a clear management structure;
- well-defined roles and responsibilities;
- discussion and agreement on performance expectations, including a balancing of authority, resources and capacities with expectations;
- appropriate monitoring mechanisms;
- agreement on how to address risks and deficiencies in performance; and
- effective mechanisms to deal with conflict and to resolve differences within the teams.

Leaders of program management teams must be ready to account for performance to those above them in the organizational hierarchy. At the same time, they must share their leadership role with others and not expect to have complete, unilateral control over decision-making. Supportive members of the team must recognize that they are also responsible and accountable to their clients, to the institution and to one another.

HSC authorities described the program management model as "complete in structural terms." They acknowledged that program teams varied in terms of levels of activity, scope of collective decision-making and the integration of the relevant health disciplines in a service delivery approach focused on the patient. This variation is not surprising given the number and diversity of program teams. We did not have the resources to investigate whether the costing of activities is now structured along program lines and whether financial accountability for program operations is upheld. Nor were we able to investigate whether performance information is generated, compiled, analyzed and utilized to guide decision-making along program lines.

Teamwork and Nurses

The Sinclair Report was critical of the subordination of the role played by nurses within the processes of the HSC. According to senior HSC officials, a number of changes have been introduced to upgrade the status of nurses within the institutions. These changes include a more prominent and active role assumed by the Vice-President and Chief Nursing Officer, the creation of a Nursing Practice Council, the participation of nurses on the joint HSC/WRHA Standards Committees, the participation of nurses on the joint WRHA/HSC Review Team analyzing the Sinclair Report, and the adoption of the multidisciplinary team approach within the program management structure. It is the last of these reforms that will be examined here. The other changes are reviewed at various other points in this report.

Participation on program teams was seen by HSC officials as the single most important way for nurses to gain influence on clinical and managerial decision-making. The Review Committee was not able to conduct a systematic and thorough evaluation of this dimension of the program management model. Effectiveness of teams in other organizational settings is seen to depend on factors like structure, leadership, process, culture/climate, communication, context and incentives. The hospital trade magazines contain many upbeat stories of problem-solving teams that drastically reduce errors, infection rates, costs and improve patient satisfaction. Whether these essentially anecdotal accounts are true is hard to determine. One empirical survey published in 1999 was based on over 75 responses from 30 teams in five hospitals in four states in the United States. Significantly, each of the hospitals was seen as a leader in terms of using teams to implement Continuous Quality Improvement strategies. The survey results suggested that teams were effective in certain kinds of problem solving. They did not, however, alter the more substantive aspects of hospital operations. Physicians and executives were found to want to circumvent the team process because they had a results-oriented and bottom-line approach and thought they knew what the answers to clinical and managerial problems were. Work teams were found to be difficult to establish and run, often requiring a significant time commitment. Insufficient attention had been paid to the information, rewards and recognition arrangements as mechanisms to promote commitment, effort and group identity. The survey results suggest that HSC might be well advised to encourage periodic evaluations of its program management teams to determine how well they are solving problems and integrating the perspectives of all their members.

Program Teams

HSC authorities indicated that in most cases, program teams were led by physicians. Nurses we spoke to suggested that the physician perspective remained dominant in the team setting. If these observations are accurate, there are a number of possible explanations for the lack of fundamental change to the governance patterns within program structures:

- physicians are professionally socialized through education and experience to follow an individualistic and autonomous approach to decision-making;
- physicians may face a "skills deficit" in terms of performing a leadership and managerial role within program structures;

- issues of power and professional turf protection may prevent more collaborative approaches;
- nurses may be professionally socialized by education, their legal and institutional status and their experience, to accept the leadership of physicians as normal or inevitable;
- there may not be sufficient institutional support to promote the team approach, including leadership from the executive level to overcome possible resistance.

We want to stress that these points are hypotheses derived from the literature and observations by the Review Committee, not confirmed findings about what is happening at HSC within the program management model.

Fully realized, the team approach to clinical governance would exhibit a number of qualities:

- all professionals would have comfort in and experience with playing a leadership role;
- there would be mutual trust and respect among professionals;
- cooperation would replace competition;
- common goals and objectives would be discussed and developed over time;
- all team members would have equal access to information and equal opportunity for input;
- conflict would be channeled in constructive directions;
- the executive would invest in and support the development of creative, problem-solving teams committed to quality care;
- the leadership would promote a "culture of accountability" by accepting responsibility themselves and following, whenever possible, a constructive rather than a blame-oriented approach to accountability for others; and
- the leadership would promote a culture of learning, quality care and continuous improvement, themes which are discussed in another section of this report.

This description may sound abstract, even idealistic, but there are techniques available for making progress.

For example, leadership and facilitative skills are not mysterious qualities that only a few gifted individuals are born with. Most people can learn to lead and to facilitate well within a group context. So-called "people skills" are essential in teamwork. The HSC has begun to offer courses on topics like teamwork and conflict management, but participation is voluntary. We asked several doctors how many of their professional peers might participate in such courses, and the answer was very few. A lack of time, a lack of financial incentives and a lack of commitment to the team model were cited as the reasons for limited interest on the part of physicians. It is worth noting that physician participation on standards committees within the WRHA has been made easier to obtain in recent years by the agreement to pay professional fees for this service. The agreement recognizes that for fee-for-service physicians, time is money. If monetary incentives are inappropriate for whatever reasons, an alternative might be to treat participation in such courses as part of continuing educational requirements, which would be particularly appropriate for physicians serving in both clinical and managerial roles.

Being Heard: The Voice of Nurses and the Nursing Council

The Sinclair Report was critical of the fact that nurses' concerns about the pediatric cardiac surgery program were dismissed by clinical and administrative leaders within HSC. Nurses were not involved in the planning and review of the program, and they lacked effective representation at the centre of institutional decision-making. Full participation for nurses as professional equals on program teams was discussed above. The Sinclair Report also called for a restructuring of the Nursing Council "to allow nurses to select its membership and to give it responsibility for nursing issues within the hospital" (p. 478). It was also recommended that the Nursing Council would provide a protected forum in which nurses could raise concerns without fear of reprisals, a matter which we address elsewhere in this Report. A third recommendation was that nurses should be represented, as doctors were, on the hospital's board of directors. This last recommendation has been overtaken by the events of 1999 when the HSC Board was disbanded and the board of the WRHA became the board for the hospital. Therefore, this section will focus on what has happened subsequent to the Inquest to the Nursing Council at HSC.

In January 2001, the Nursing Practice Council at HSC was restructured. Details on the purposes, structure, activities and reporting relationships are given in Appendix C. We see the renewal of this Council as a positive first step. At the time of our review, the Council was just getting underway and the extent to which it is effective will depend on how the concept is implemented. We offer the following preliminary observations.

The purposes and activities presented in the Terms of Reference for the Nursing Practice Council raise the questions of whether the Council is meant to be consultative and advisory, and not have real decision-making power. Phases like "to provide a forum" and "to monitor" imply a consultative role whereas other phrases like "to approve policies and procedures as they relate to nursing practice" imply a decision-making role. Ambiguity concerning the authority of the Council may reflect the need to gain initial support from different stakeholders within HSC, but it may also lead to eventual disappointment with the Council if it fails to "live up" to different sets of expectations. If for legal, structural and "political" reasons, the Council is being given "only" an advisory role, this should be made clear. A Nursing Practice Council that serves only as a forum for the exchange of information and opinion and for the provision of advice, could still have significant influence. This will require the leadership of the institution to see the Council as a vital forum for genuine dialogue and to act in a responsive manner to its recommendations. By dialogue, we mean a situation in which everyone engages in candid, respectful and honest conversations about subjects that really matter. The Council must not be simply a public relations exercise. Dialogue should involve bringing unspoken concerns, fears, tensions and problems to the surface. Dialogue is not about winning arguments by beating down opposing views. It is about inquiry and the search for insights. Ideas are discussed openly and individuals listen carefully. In short, dialogue helps a group think together and this is what the nursing Practice Council should promote.

Among the functions of the Council in relation to professional practice is the provision of "a forum for the resolution of nursing issues." It is our understanding that the designers of the new Nursing Practice

Council did not intend for it to become the protected forum in which nurses could raise issues of concern without fear of professional reprisal. We also believe that the new Council, by reason of its size, composition and other responsibilities, is not the right body to deal with complaints about misconduct or incompetence. In the section of our Report entitled "The Duty of Loyalty versus the Duty to Inform" we recommend that the HSC adopt an internal disclosure policy that supports people from all occupational backgrounds at all levels within the institution bringing forth legitimately held concerns through the normal channels and alternative routes without fear of damage to their careers. The Nursing Practice Council could not offer the procedural protections needed to make an internal disclosure policy work effectively both in encouraging people to come forward and dealing fairly with their concerns. Therefore, elsewhere in this Report, we propose an alternative mechanism.

In addition to her participation on the Nursing Practice Council, the Vice-President and Chief Nursing Officer (Heather Crawford) has recently instituted monthly lunches to allow invited front line nurses to meet with the President, Vice Presidents and other members of the HSC executive on a regular basis. This new initiative will hopefully make nursing staff feel that the executive is approachable and will also allow the leadership to gain perspectives and insights which might not flow through normal channels.

In summary, we support Judge Sinclair's call (p. 496 and 497) for ongoing initiatives to develop team concepts and to improve team performance because clearly in 1994 human factors played a significant role in contributing to negative surgical outcomes. Beyond the prevention of error, however, more effective teamwork will contribute to improved learning, productivity and morale. To be effective, the concept and practice of teamwork must become embedded in the HSC culture.

CULTURE, CLIMATE AND LEADERSHIP AT HSC

On page 492 of his Report, Judge Sinclair observed that "leadership, teamwork, communication and decision-making are recurring themes. They are not side issues, not matters of mere personality differences, but central issues. Where these issues were not resolved, they often led to tragic results." We agree. We also recognize that changing the culture and climate of a large, diversified institution like the HSC is not something that can be done quickly and easily.

Culture is a buzzword, used differently and sometimes in contradictory ways. By culture, we are referring to the assumptions, beliefs, values, norms of behaviour and the social structure (reward systems, career paths, communications networks, etc.) that condition and shape behaviour within organizations. Culture is powerful because it reflects taken-for-granted ways of seeing the world and people's customary behaviour based upon assumptions about "how things are done around here." People don't often express these assumptions directly. Espoused values may be contradicted by actual behaviour and there may be clashes among sub-cultures within large, diverse organizations.

Climate is closely related to culture. The term refers to the pyschological atmosphere or "feel" of the organization. It involves the physical layout of the organization, but more importantly the nature of the interpersonal relationships. In the case of HSC, there would be a climate among employees within the institution at large, within its sub-units and between the institution and its clients. Climates can be trusting,

respectful, cooperative, open, supportive, forgiving and caring. Or climates can be closer to the opposite of these positive values. Cultures and climates tend to become apparent only when critical events occur, when sub-cultures clash and when leadership changes are made.

The publication of the Sinclair Report and the internal review it has prompted represents an opportunity for HSC to examine its culture and climate in a more systematic, formal manner. There are techniques available to map the contours of its culture(s) and to change culture and climate in order to influence behaviour in positive ways. Among the possible techniques are the following:

- conducting of a cultural audit to identify the taken-for-granted assumptions and shared values that influence employee behaviour;
- examining leadership styles;
- attention to the cultural orientation of people recruited to the institution;
- examining whether structural reforms are congruent with cultural changes;
- analysing how issues management reflects cultural values;
- reviewing of the rewards and recognition system to determine if it supports espoused cultural values;
- using rituals and ceremonies to reinforce desired cultural values;
- examining how "sentinel events" define and shape people's perception of what really matters within the institution;
- using communications as a strategic activity to guide organizational change, not merely as a public relations tool to defuse conflict or enhance the image of the institution to its employees and outside stakeholders.

Cultural change will not occur simply through mission statements, speeches or newsletters, but will only occur by altering the everyday policies and practices impacting the beliefs and values that guide employee actions.

Leaders must not only espouse certain values, they must express them in their daily actions. What people experience as the climate and believe is the culture of the HSC will determine whether the benefits of the new program structures are fully realized and sustained. The HSC officials whom we met seem to accept these points and recent actions are moving the institution in the right direction. Considerations of leadership, culture, climate, communications and the management of conflict need to become a more prominent part of an integrated strategy for organizational change at HSC.

Creating the Learning Organization

It seems ironic to suggest that a hospital would face difficulty in fostering a culture that supports individual and organizational learning, but that is what Judge Sinclair claims to have observed at HSC. Issues of learning arise at a couple of points in the Sinclair Report. There is the issue of the "learning curve" for a new surgeon and a surgical team, which we have discussed in the section of our Report entitled "Recruitment, Selection and Training of Surgeons."

Here we wish to examine the somewhat philosophical, but crucially important reflections of Judge Sinclair on "Error, Accident and Humanity" found on pages 487 to 495 of his Report. There are both practical cultural and procedural reforms which flow from this discussion.

As the Sinclair Report notes, risk and error are an inevitable part of surgical procedures, especially of difficult procedures like pediatric cardiac surgery. We would add the observation that not all unwanted outcomes result from human error. Because of the limits of medical knowledge and the lack of perfect predictability, there are situations where unforeseen and perhaps uncontrollable factors contribute to outcomes which were not anticipated. We know, for example, of the important role that the strength and will of a patient to live can play in dealing with illness. Doctors and health professionals are not infallible and cannot always achieve miracles. Yet, as the Sinclair Report notes, the medical culture reinforces the belief that physicians and surgeons must perform without error. To admit to mistakes raises questions of competence and therefore undermines the authority of the medical practitioners. In a classic study of over 30,000 records from 51 acute care hospitals in New York, it was found that adverse events leading to death or disability occurred in 3.7 per cent of hospital stays, with one-quarter of the events attributable to negligence. Most medical mistakes are relatively harmless. They are not serious enough to produce major complications or they are detected early enough for corrective action to occur. When you add these "near misses" to the identified incidents of actual harm, it becomes clear that medical practice, especially in high-risk fields, may be a science but it is one which remains significantly affected by human factors.

The Sinclair Report identifies two approaches to dealing with medical errors: blaming and learning. Too much emphasis on blaming will lead the individuals to minimize their involvement and liability for errors of commission or omission. For example, the critical incident reporting policies in the HSC were meant to identify and deal with identified mistakes and with near misses, but the Sinclair Report observes that in 1994, the use of incident reports for learning purposes was not an engrained component of the HSC. Only one incident report was filed in connection with the 12 cases of infant deaths in the pediatric cardiac surgery program. Problems were often not charted and were not referred to Standards Committee. A culture which saw the surgeon as the "infallible captain of the ship" prevented open discussions of problems because that would be seen as a challenge to the authority and legitimacy of the surgeon.

We have repeated the findings of Judge Sinclair about dealing with error to reinforce the point that culture plays a key role in organizational learning. Edgar H. Schien, probably the leading authority on the concept of organizational culture, wrote in 1993 that:

> "Organizations do learn within the set of assumptions that characterizes their current culture and subcultures. But if any new organizational responses are needed that involve changes in cultural assumptions or learning across subcultural boundaries, dialogue must be viewed as an essential component of such learning."

For individual and organizational learning to be more strongly promoted, there must be cultural change at the executive level, within sub-units and across the entire organization. Learning organizations formulate objectives and appraise performance through methods involving shared inquiry and the integration of different perspectives, whereas the traditional medical culture emphasizes physician autonomy and individual judgement. Organizational redesigns meant to collapse the walls and status distinctions among different

functions and personnel may have little enduring effect unless they also change the specialized, fragmentary, sometimes competitive mental models that led to the erection of the walls in the first place.

A crisis like that which occurred in the HSC during 1994 should produce immediate changes within an organization, but the longer range challenge is to instill a culture of continuous learning and improvement. We acknowledge that this is far more easily said than done given the basic structural features of a large hospital like HSC and the deeply entrenched nature of certain key features of its culture. After the shock of the crisis passes, there is the danger that defensive rationalizations will prevent the organization from considering fundamental changes. However, the need for collaboration, learning and improvement is a message and a commitment that the leadership of the institution must demonstrate continuously in their words and deeds.

Critical Incident Reports

Judge Sinclair wrote that one of the aims of his Report was to contribute to increased openness about error. A mechanism to promote such openness is the strengthening of the HSC's policy on the reporting of critical incidents. A briefing note provided by HSC to the Review Committee noted that activity has been ongoing since 1997 to improve the Critical Incident Reporting System. The briefing note is attached as Appendix D to this section of our Report. With the full implementation of the new system in January 2001, the HSC authorities believe that they have complied with both the spirit of corporate learning and the detailed procedural requirements proposed in the Sinclair Report.

Extensive educational efforts have been undertaken to familiarize managers and front-line staff with the policy, and their responsibility to comply with its procedural requirements. The policy aims to identify a specific manager as "the owner" of an incident and make that individual responsible for follow-up action. In the past, incident reporting was seen as primarily a nursing responsibility, but the new system encourages all team members, including physicians, to come forward with concerns. In our meeting held at HSC, a senior official observed that most physicians practising in HSC do not yet see themselves as part of the new system. To encourage participation, the critical incident process is designed to be non-blaming and not intended for disciplinary purposes. Information from incident reports is scanned into a computer database and quarterly trend reports are produced. The Critical Case Review Committee (CCRC) receives the data and every second month, they discuss a case to determine what went wrong and why. The CCRC is co-chaired by a physician and a nurse and provides an opportunity for cross-disciplinary learning. The effectiveness of the policy, including the generation and utilization of the data, needs to be continuously monitored.

In summary, we were impressed with the new policy for critical incident reporting within HSC and with the thorough manner in which the policy is being implemented. The hospital has worked to meet part of the recommendation of the Sinclair Report on this issue. However, we could not find in either the briefing note or the policy statement itself any measure to ensure that "there is no personal or professional jeopardy to the person who is making an [incident] report" (Sinclair Report, page 498). In another section of our Report, entitled "The Duty of Loyalty versus the Duty to Disclose," we recommend that HSC should devel-

op a policy on internal disclosure to promote openness and candor concerning problems that might arise. If reliance is to be placed on the critical incident process, individuals must feel freer than they did in 1994 to come forward with concerns and not perceive that they will be stigmatized and penalized for doing so. We recommend that the relevant HSC officials consider strengthening the critical incident policy by including protection against retaliation for individuals who raise legitimate concerns. Physicians need to understand, endorse and participate in the critical incident reporting system.

Quality Assurance

Critical incident monitoring is now a widely used quality assessment and quality assurance methodology in hospitals. Ideally, data from critical incidents can be used to focus on particular sorts of events, to examine trends and compare performance. The aim would be to alter individual or organizational practices or systems to prevent future incidents and improve the quality of care. However, critical incident monitoring does not, by itself, provide a full picture of the quality of care. It focuses on the processes of care, not on the outcomes. It highlights poor quality care, but does not of itself help to define what constitutes good quality care.

Quality assurance programs have been a part of hospital operations for some time, with the reliance upon them growing during the 1990s. Such programs have gone by various names in different institutions, such as Total Quality Management (TQM), Continuous Quality Improvement (CQI) or simply Total Quality (TQ). By late 1992, almost half of the respondents in a survey of 1,300 Canadian health care institutions reported that they had adopted or were considering implementing a quality initiative. However, more recent evidence suggests that the rate of adoption and the degree of integration of quality improvement programs in hospitals has slowed. Having a formal quality program does not guarantee an enduring organizational commitment to continuous quality improvement.

Although many Canadian hospitals have adopted the principles and techniques of the quality movement, surveys suggest that too few hospitals use such programs to secure excellence in overall organizational performance. TQ programs launched with great fanfare have floundered in hospitals that are preoccupied with budgetary cutbacks, workforce reductions and structural reorganizations. Quality initiatives have ended up being relegated to a small unit or committee, being under-resourced in terms of money, staff, time and technology, and being "waited out" by many health professionals as just the latest "managerial fad" which soon will pass, as others have done before it. Despite the voluminous literature advocating the adoption of quality programs and the numerous testimonials concerning their success in particular institutions, there have in fact, been very few attempts to evaluate systematically the effectiveness of such programs in improving hospital performance. A 1997 review of TQM programs in hospitals in six European countries reported that none of the "leading quality hospitals" had fully implemented TQM as defined by the "quality gurus." Many had very different understandings of the aims of TQM and there were serious disagreements over the conditions needed to make such programs work.

There are a variety of possible reasons why quality programs have not been the "quick fix" they were claimed to be:

- defining, measuring and improving quality in health care is more difficult and controversial than in manufacturing processes where the quality movement started;
- hospitals differ from private sector firms because the service providers (physicians, nurses and other health professionals) are, to varying degrees, already empowered and each have their own definition of quality;
- in such circumstances quality becomes "contested territory" over which professions compete for ownership and definition of quality;
- physicians have trouble identifying with and committing to quality initiatives, seeing them as a threat to their autonomy, as a means for managerial control, and/or as a method of cost-cutting;
- there is uncertainty over what structures are necessary to support quality initiatives; whether quality should be a line department concern or a horizontal staff function;
- the training in quality theory and methods is often not sufficient or appropriate; it was not linked to practical day-to-day tasks;
- there is lack of top-level executive commitment in terms of resources and support for quality programs during tough times; and
- the jargon and concepts of TQ are "foreign" and inappropriate in the hospital setting.

Two key points seem to emerge from the small number of more objective and systematic evaluations of quality programs within hospitals. First, there is no "one best way" to pursue quality in hospitals. Each hospital must adapt quality concepts and techniques to its own institutional context. This suggests the value of pre-program assessment and planning. One constant of apparently successful TQ programs is top management commitment and constancy of purpose. The second point is the need to obtain "buy in" from physicians, especially those performing as formal and informal leaders within the hospital. This will involve finding the right balance between management and professional ownership, and definition of quality. Anecdotal evidence suggests that achieving a "quality culture" and breakthroughs in terms of performance takes anywhere from three to five years and some advocates in the quality movement described it as a "continuous journey" without a finish line.

Having set a framework, we now turn to a description and assessment of the quality assurance efforts at HSC.

Quality Asssurance at HSC

A concern to promote quality care has been an official commitment within HSC since its founding in 1973. Quality assurance activities were meant to be part of all medical programs within the institution. Originally, the definition of what constituted quality care was based on the standards of the physicians and to a lesser extent, on those of the nurses. With the rise in popularity of approaches like Total Quality Management and continuous improvement, the patient's perspective was brought more into the quality equation. "Making It Better" (MIB) was a short-lived quality initiative launched within HSC in the early

1990s. The objective was to improve "customer service" and the quality of care/services through "process improvements." MIB was a brief experiment, because it was supplanted in 1993–1994 by the Work Restructuring Program (also known as the Connie Curran Project – named for the U.S.-based health consultant who represented the American Practice Management Group). The primary objective of the Work Restructuring Project was to reduce costs by 15–20 per cent of total budget; quality improvements were a secondary consideration.

Subject to the Curran Project, HSC implemented the Program Management model, which included efforts to transform the values of the institution towards more teamwork and promote continuous improvement in patient care services. In structural terms, quality improvement was and remains both a central and a decentralized responsibility. At the central, corporate level, there existed for three years an Integrated Quality System Steering Committee. In March, 2001, this body was renamed the HSC Integrated Quality Council and revised its terms of reference. Among its functions are the following:

- recommend structural changes to improve quality;
- set annual quality objectives for clinical programs and services;
- monitor trends in quality improvements; and
- refer corrective action to line managers.

The HSC's Integrated Quality Council meets bimonthly. It reports directly to the COO and the Executive Team at HSC and also collaborates with the WRHA Quality Council.

The existence of a central quality council is not meant to remove responsibility from program managers for incorporating quality considerations into their ongoing activities. There is a small staff capability, called Quality Support Services, to assist line managers with the development, generation and reporting of quality, risk and utilization data. The Quality Support Services unit is also responsible for coordinating the process of preparing the HSC survey for the periodic accreditation by the Canadian Council on Health Services Accreditation. In terms of the division between line and central responsibilities, line managers are expected to ensure an integrated approach to quality/risk within their programs whereas the Integrated Quality Council promotes the concepts, monitors performance and deals retrospectively with problems.

The Review Committee did not explore HSC's recent quality efforts in great depth. In terms of some of the obstacles to successful quality initiatives mentioned earlier, we would offer the following observations. Quality assurance was part of the official structure of HSC back in 1994, but its principles and practices were missing from the pediatric cardiac surgery program. We think that the current structure for quality assurance within HSC – which combines line responsibility with corporate promotion and monitoring – offers the best potential for ensuring that quality concerns are integrated into practical, everyday decision-making as opposed to being simply a "management hobby horse" for corporate staff to ride. There appears to be top-level executive commitment to the goals and efforts involved with ensuring quality care and services as reflected in recent changes to the Quality Council. Without a full survey, it is not possible for us to determine the extent of the integration of quality thinking into the culture of HSC and, in particular, the extent to which physicians, who most often lead program teams, have "bought in" to the approach. We suspect that the progress on this level is uneven. Collaboration with the Quality Council of the WRHA is a

potentially valuable arrangement because it represents knowledge from other Winnipeg hospitals and leverage to maintain momentum. With the support of the WRHA staff, the HSC quality team might consider a multi-year cycle of quality audits of specific clinical and support service areas.

A Child Health Program Quality Initiative

HSC authorities have developed a funding proposal for a Child Health Program Quality Initiative.

The Initiative would allow for the generation and analysis of data on the quality of care and provide evidence on which to base changes. Comparisons to pre-determined standards and to programs elsewhere would be possible. Five Children's Hospitals across Canada currently participate in a pediatric data base project begun in 1995. Were the HSC to join the project, the data would allow for "benchmarking" to other institutions. The data to be collected in the HSC Child Health Program would be more relevant and timely than the current information from the WRHA Planning and Information System.

The HSC proposal states the start up costs of creating the Quality Initiative and joining the Pediatric Data Share Project as $43,000. Beyond this initial investment, annual operating costs would be $260,000. The Review Committee sees this as a worthwhile initiative, which is necessary if HSC is to become a centre of excellence in pediatric care and is able to provide assurances of the highest possible quality care compared to other Canadian programs.

Risk Management

Risk management is the systematic process of identifying, evaluating and addressing potential and actual risk through a well designed program that prevents, controls and minimizes risk exposure. Risk can arise in a variety of areas: clinical programs, use of equipment, facilities, procedures (eg. disposal of hazardous waste) and organizational characteristics (training, level of experience, communication). Risk may be said to be the likelihood of an event occurring that may stand in the way of an organization achieving its objectives. Risks and adverse events affect all individuals within an organization because, even if individuals are not directly concerned with an incident or event, they are indirectly affected by the time and monetary costs of correcting mistakes, the loss of effectiveness, the loss of reputation and the reduction of public confidence in the service being provided and the organization as a whole. It is therefore important that every employee in an organization be encouraged to assume responsibility for risk identification and risk reduction. Hospitals, in particular, need to develop a pro-active safety culture in all aspects of their operations. For the purpose of this report, we are concerned mainly with clinical risk management.

Hospitals need a clinical risk management strategy, a risk management program, the organizational capacity and staff capability to conduct risk analysis and the clear designation of responsibilities for dealing with risk management issues in different areas. Beneficial outcomes of an integrated risk management strategy and program include:

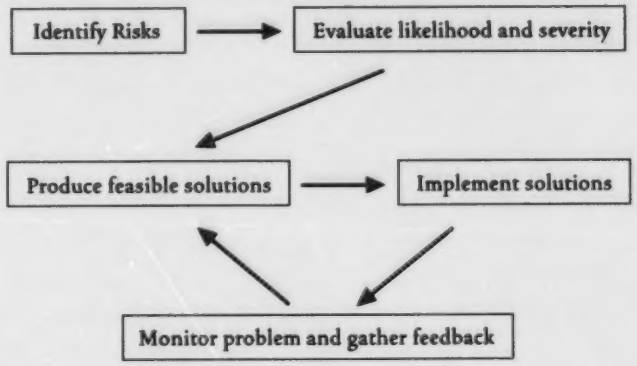
- identifying and ranking risks;
- reduced patient harm and dissatisfaction;

- preventing poor use of staff, time, and money;
- protection from liability and litigation;
- making staff more safety conscious; and
- protection from bad publicity.

Successful adoption of a risk management strategy requires the cooperation of key hospital staff: physicians, nurses, technicians, managers and risk management specialists.

The risk management process involves a number of stages as outlined in Figure 3. The first stage involves **Risk Identification**. This can be done through the analyses of patient records, critical incident reporting, questionnaires, interviews, checklists, risk grids, process evaluations, etc. Incident reporting and record analysis may detect different events. A U.K. study estimated that voluntary reporting captures approximately 30 per cent of untoward events, but as the earlier discussion of incident reporting suggested, many staff in hospitals consider "incidents" part of everyday practice, with which they know they can cope, and therefore reports are not filed.

Figure 3 STAGES OF RISK MANAGEMENT



Once identified, risks can be handled in a number of ways: eliminated (in a small minority of cases), reduced, limited in their impact, or accepted as tolerable, especially if it is not cost-effective to create a totally risk-free situation. The formulation of appropriate organizational responses to risks requires knowledge and skills in the field of risk analysis, a discipline which is becoming more specialized and rigorous over time, especially in the health field where litigation costs are rising steadily. The purpose of risk analysis is to grade the likelihood and the severity and the cost-benefit in time and resources to eliminate or minimize risks. Based upon risk analysis, an action plan must be developed and responsibility must be assigned for its implementation. The plan must identify the resources needed to achieve its objectives – people, training, equipment, funds, etc. The results of a risk management plan must be monitored and, on the basis of evidence, the plan must be revised to ensure that it is achieving its aims.

Recent problems in the hospitals within the National Health Service (NHS) in the U.K. have sparked a number of studies of clinical risk management. There is not the space here to review these studies in detail. Some of the key findings are:

- 85 per cent of the Trusts (hospitals) had appointed a Clinical Risk Manager (CRM), most of whom had a clinical background, but only 11 per cent had formal training in risk management;
- most Trusts had systems for reporting critical incidents, but it was not always clear whether and how these reports were used;
- physicians needed to become more involved in the risk management process;
- nurses and nurse managers seemed to be reluctant in promoting and carrying out risk management strategies;
- here were continuing problems in the training of health professionals in the use of medical equipment, with consequent risks to patients; and
- as yet, there is little robust evidence that risk management prevents adverse outcomes or delivers benefits like reduced litigation.

The absence of compelling evidence about the benefits of risk management is not a persuasive reason to do nothing since we are talking about the safety and health of patients, staff and visitors to hospital facilities. Also, the benefits of risk management programs may flow through improved quality of care. For this to happen, there must be an integration of several types of activities: critical incident reporting, risk management procedures, standards committees and service quality initiatives of various kinds.

With this preliminary discussion as background, we turn to an examination of the current risk management program at HSC.

Risk Management at HSC

The Review Committee was provided by HSC with a 27-page "Risk Management System" document dated May, 1998. Updates to sections of this document have been produced over the years.

The document identifies the aim of the risk management system as contributing to quality care by protecting patients, visitors and staff from risk and by preserving the physical and financial resources of the institution. The HSC risk management system consists of three components:

- systems designed to empower managers to address risks at their source;
- processes for ensuring staff competency and for monitoring; and
- risk service support centres staffed with specialists in specific risk fields.

Risk management is integrated into the hospital's general management structure. A formal risk analysis process exists to guide line managers in identifying and dealing with risk.

On paper, the elements of a sound risk management system exist at HSC. Recent reforms, like those to the critical incident reporting process, signal a concern for diligence in dealing with risk. Authorities at HSC acknowledge that stronger risk management strategies and better information sources on risk need to be

developed. One of the problems cited is funding. Additional funds are required to establish a readily accessible data base to monitor patient status, outcomes, morbidity, etc.

This issue raises the wider problem of the inadequacies of the existing information infrastructure within HSC and other parts of Manitoba's health network. If the aim of the Government of Manitoba is to move towards more objective, evidence-based delivery and monitoring of health care, significant investments in information technology and staff training will be required.

THE PATIENT EXPERIENCE AT HSC

Every day hundreds, if not thousands of people from diverse backgrounds enter the HSC to obtain an enormous variety of medical procedures and health services. It is not really possible, therefore, to talk about a "typical" HSC patient experience, but we want to comment on the "climate" of the institution as it relates to interaction with patients. By climate we mean the psychological environment in which care is sought and provided. "Patient climate" is a function of both the physical structure of the hospital and the behaviours of the various employees.

Anyone approaching HSC for the first time could be easily confused and intimidated by the scale and complexity of the institution. The institution covers 14.2 hectares or about 12 city blocks. In addition to the four founding hospitals – Winnipeg General Hospital, the Women's Hospital, the Children's Hospital of Winnipeg and the Manitoba Rehabilitation Hospital – the site includes University of Manitoba faculties of Medicine, Dentistry and Medical Rehabilitation, CancerCare Manitoba, the Cadham Provincial Laboratory and numerous other buildings. The institution has been built piecemeal and seems to be perpetually under construction. Buildings connect to one another in bizzare ways. Finding parking and finding your destination through a bewildering array of outdoor walks, indoor hallways/tunnels and adjoining buildings in which the floor levels do not match can be a frustrating experience, as the Review Committee discovered when it conducted an unguided walkthrough of the facility. We tried to imagine how difficult, indeed scary, it would be for most families of infants facing delicate and risky heart surgery to arrive at HSC for the first time. We recalled being told by two women of aboriginal descent, who spoke little or no English, how they had flown unescorted from the North, taken a taxi to the hospital and tried to find the Children's Hospital.

HSC authorities have taken steps to make the facility more "patient friendly." There are several information booths, colour codes for different buildings, wall maps, signage on the main thoroughfares and a "service guide" pamphlet, which contains a map of the facility. While all of this helps somewhat, the families involved with the tragic events of 1994 all found the hospital to be a complicated and intimidating institution. A family who took their newborn daughter to a Saskatoon hospital described a model which HSC should consider. In Saskatoon, a worker assigned from the Neo-natal Intensive Care Unit, met the family at Admissions, took them on a tour of the facility, confirmed their accommodations at Ronald McDonald House, introduced them to the surgeon, stayed with them while the surgeon explained the procedure, answered questions that arose after the surgeon left, provided them with periodic updates during the surgery and met with them and the surgeon to "debrief" and make arrangements for follow-up care. "Putting a

human face" on a big, impersonal institution and helping to ensure support from admission to discharge would be extremely helpful for families coping with a highly stressful and emotional situation. We recognize that there are staffing implications involved with adoption of this model. However, the cost of maintaining a two-person office on a seven-day basis would not seem to be a huge expense in a budget of over $300 million annually.

The need for support services for families dealing with a crisis was a message that was repeated many times during our conversations with the families involved in the events of 1994. We heard stories of dedicated and caring nurses who spent off-duty time with families before and after surgery. But we also heard of physicians and other health professionals who did not treat families with respect, did not provide adequate and understandable information and pressured families into making rush decisions. At other points in their experience, the parents felt very much alone, not knowing what was to happen next or who to turn to for advice.

It was important for the Review Committee to hear the families' interpretations and perceptions of the events of 1994. We did not listen to all the other individuals involved with those events, as Judge Sinclair did, so we are not in a position to offer a fully informed judgement as to why the families felt so vulnerable, mistreated and misled by people working in HSC. The Sinclair Report makes it clear that the families were justified in their complaints about the hospital system. Throughout their experiences, the families hoped for three things – competence, communication and care. Issues of professional competence and of patient-physician communication are addressed elsewhere in this report. On the matter of creating a caring climate or atmosphere, we recognize the difficulties of humanizing a large scale institution like HSC. We also acknowledge that budgetary realities are such that extensive support staff for patients and families may be difficult to fund. However, we were very disturbed by the families' stories of being alone during critical moments, especially when they learned of the deaths of their children. In some cases, these events happened when "helping" professionals such as social workers, grief counsellors, and chaplains were not available at night. First Nation and Inuit families faced the additional burden of coping with language and cultural barriers without the help of the Aboriginal Services Department. The most difficult moment is when families learn of the death of their child. How the news is communicated and the nature of the support provided is crucial. Parents are in shock. They are confronted with complicated and difficult decisions – dealing with autopsy permission forms, notification of other family members, making funeral arrangements, and in some cases return travel to their home communities. Even a single individual, who is perhaps on call after hours, could be of enormous help to families trying to come to terms with the loss of a loved one and confront the practical matters that must be done.

The Patients' Representative Office at HSC

Since 1990, there has existed at HSC a Patient Representative Office (PRO). A hospital document describes the role of the PRO as follows: "to develop effective relationships between HSC patients and staff by:

- investigating patient complaints and directing requests to the appropriate staff;

- assisting staff with patients/families who wish third party involvement in the resolution of their concerns;
- participating in activities to reduce future complaints; and
- assisting medical legal staff by identifying patients who are high-risk for litigation.

The existence of the PRO is made known to patients in several ways. The Office is described in the HSC Admission Handbook, which is available at every bed. Ward nursing staff also have PRO cards to hand out to patients. The cards explain how the office can help. The HSC pamphlet on informed consent also notes the existence of the Office. Unit managers are usually the first point of contact when patients have concerns and they are expected to refer patients to the PRO if matters are not resolved expeditiously.

There was confusion among the parents involved in the events of 1994 as to the role of the PRO. Some referred to it as the "Patient's Advocate." They felt betrayed that the Office did not in fact champion their cause; instead they saw it as acting to protect the hospital. Employees of HSC working in the PRO cannot assume an advocacy role on behalf of patients and openly challenge the authority structure of the hospital. Their role is that of a neutral and objective "broker" when there are unresolved disagreements between patients and HSC staff. For the PRO to perform more effectively in this "go between" role requires a number of conditions:

- the PRO should be outside the regular management structure and report directly to the Vice-President and Chief Nursing Officer;
- the PRO should be covered by the internal disclosure policy (recommended elsewhere in this Report) to ensure that there is a safe channel of communication and that they are not subject to reprisals for raising issues to higher levels;
- the PRO should track complaints over time and report regularly to the Vice-President to ensure that persistent problems are detected and dealt with as early as possible; and
- the PRO should have pamphlets available and provide advice on the services of the CPSM and the Office of the Provincial Ombudsman.

It should be noted that hospitals now fall within the mandate of the Provincial Ombudsman. This was not the case in 1994. With the adoption of the *Regional Health Authorities Act* in 1997, hospitals were brought under the authority of the RHA Boards and were thereby deemed to be government "agencies" under the terms of the *Ombudsman Act*. The Ombudsman is not an advocate for complainants. Rather, the Ombudsman is an impartial investigator with the powers to discover the facts of a case and determine an appropriate resolution which is recommended to the relevant authorities. The Ombudsman cannot force public agencies to comply with recommendations, its influence depends on persuasion and publicity. The critical features of the Ombudsman Office are its independence, accessibility, flexibility and credibility. These attributes are important because even when complaints are not upheld, the individuals involved are more likely to believe that they have been heard and fairly treated. The Ombudsman is an appeal mechanism to be used when internal complaint procedures have not resolved issues and when the complaint procedures of the CPSM are not appropriate because the disagreement involves managerial rather than clinical issues.

Further recommendations on the protection of patients rights are found in our chapters entitled "The Issues of Informed Consent," "The Role of the College of Physicians and Surgeons of Manitoba" and on "The Duty of Loyalty versus The Duty to Inform."

The Executive of the HSC

The Sinclair Report records the testimony of the President and Vice Presidents at HSC back in 1994 to the effect that they were not adequately informed of problems in the pediatric cardiac surgery program. To the extent that they were aware, they believed that the problems were being dealt with by the relevant department heads. The President of HSC at the time told the Inquest that the withdrawal of services by the anaesthetists which lead to a review of the program should have been brought to the attention of the hospital's Board of Directors. It was also noted in the Sinclair Report that the problems in the program were not referred to the Quality Assurance Committee of the Board of Directors (Sinclair Report, pp 457 – 460).

Both the executive and the Board of Directors represent crucial links in the chain of accountability leading back ultimately to the Minister of Health, who answers to the elected representatives of the public in the Manitoba Legislature. When executives fail to ensure that problems are being dealt with appropriately and fail to inform their Board of Directors and possibly outside institutions, the accountability process breaks down. For accountability to work as intended in a health care system of multiple, interdependent institutions and actors there is a clear requirement for sharing information widely and good communication concerning risks of various kinds. Both internal and external accountability processes exist to provide the public with the assurance of competent and safe care, contribute to the detection of errors, promote individual and organizational learning and galvanize subjective norms of responsible behaviour among health providers and health administrators by making them answerable for their actions and inactions. If the accountability system worked at all in 1994, it worked at best inadequately and belatedly.

A description of the principal functions of the President of the HSC is set forth on page 79 of the Sinclair Report. The job description includes providing leadership, ensuring compliance with statutes and regulations, maintaining contacts with external agencies, protecting the resources and reputation of the institution, helping the board of directors to set objectives and ensuring that those objectives are met. The leadership and management challenges involved with running a complicated, tertiary hospital like HSC are enormous. During 1994, the HSC was in the process of implementing a major reorganization along with significant budgetary cutbacks. A great deal of time and energy of the senior administration was consumed by these developments. However, these facts have not, and should not, be used as a justifiable excuse for neglect of a fundamental duty of ensuring competent and safe patient care. There will always be "urgent" issues on the institutional agenda of a facility like the HSC, but they should not drive out attention for its fundamental mission "to enhance the health and individual well being and dignity of residents of Manitoba ..." (HSC Mission Statement).

As of January 1999, the Chief Administrative Officer of HSC assumed the title of Chief Operating Officer (COO) rather than President. The HSC Board of Directors was disbanded. The COO of the HSC now reports to the Board of Directors of the WRHA through the Chief Executive Officer of the WRHA. At

the time of the writing of this report, the other hospitals in Winnipeg continued to have their own board of directors, although the future of those boards was under review. In Chapter Two of this report dealing with overall accountability within the health system, we discussed the need to further clarify the working relationships between hospitals, RHAs, Manitoba Health and the Minister of Health if sound accountability requirements are to be met. In the case of the HSC, the reporting relationship of the hospital's COO to the WRHA is a recent development and understanding the full and exact nature of the working relationship between the two institutions is difficult from the outside. A topic for further study is whether the WRHA Board of Directors conducts appropriate and sufficient ongoing scrutiny of developments within the HSC given the wider range of responsibilities of the regional board compared to the former hospital board. The responsibilities of the WRHA Board within the health care governance system will become even more extensive should the boards of directors at the other Winnipeg hospitals be devolved.

Concluding Thoughts

The HSC is a large, specialized, decentralized and dynamic institution about which it is difficult, perhaps even inappropriate, to make generalizations. In this section, we have examined the interplay of structural, process and cultural changes at the HSC. Leadership, communication and conflict management were seen to be crucial requirements for successful change. Resistance to change can arise from a number of sources and can take a number of different forms. The structural features of a multidisciplinary team approach to program management appear to be in place. There remains the challenge of creating a culture and a climate which supports a team approach to the design and delivery of medical programs. The characteristics of effective teams are well known: shared leadership, open communication, self examination, mutual respect and trust, disagreements focused on ideas and methods rather than personalities, commitment to the task, the courage to confront difficult issues, and the willingness to devote whatever effort is necessary for team success. Not all program teams will move in the same direction at the same pace. The leadership of HSC at all levels will have to give continuing attention to the development of the culture and climate which supports open and creative problem-solving.

A key in this process will be to convince physicians that many of their own professional and personal interests will be served by participating more fully in the change process. Hospitals have always been characterized by a certain amount of tension between physicians and administrators. This tension has grown during the past several decades due to budgetary restraints, reorganizations, new managerial approaches like TQM and continuous improvement, and the growing emphasis on "customer service" measured by surveys of patient satisfaction. These developments clash with the core belief of most physicians that hospitals exist to serve professionals and to meet professional standards.

The leadership at the HSC must continue their efforts to convince physicians that changes to structures, processes and cultures could lead to less risk, higher productivity, less frustration and higher patient satisfaction. Rather than being constrained by externally-imposed rules and measures, through fuller participation on clinical program teams, physicians could play a leadership role, identify barriers to quality improvement, measure what works and implement change that is backed by solid data and stands up to external scrutiny.

The majority of physicians who work at HSC are not directly employed by the hospital. Doctors are granted hospital privileges to admit patients and to provide services for which they bill Manitoba Health. Some doctors supplement their fee-for-service income with salaries paid by the University of Manitoba's Faculty of Medicine where they hold teaching appointments. The key point is that most doctors, unlike nurses, are not directly controlled by the hospital, yet they exert enormous influence over the resources and the reputation of the institution.

The involvement of the majority of physicians in the processes of institutional change will always be limited by the perceived adverse impacts on their professional roles, autonomy, time and incomes. On the question of doctors' incomes, we are not suggesting that all or most doctors are greedy. The majority of physicians, we believe, decide on medical actions out of a desire to help and serve their patients. However, the fee-for-service model of remuneration provides an incentive to do more rather than less. In expensive and high-risk fields like pediatric cardiac surgery, there may be additional pressures on surgeons and other specialists to do more in order to maintain the critical mass of patients needed to sustain positive outcomes and to justify the existence of a particular medical program. The reward and recognition systems which operate within hospitals not only provide incentives for certain kinds of behaviour, they also contribute to shaping the organizational culture. There is no "perfect" remuneration system which fits all types of programs and situations. On the issue of alternative remuneration arrangements, readers are referred to the section of our report entitled "The Recruitment, Selection and Retention of Physicians."

Recommendations

The Review Committee recommends that each Program Management division develop an "accountability map" which designates responsibilities and traces the lines of reporting back to the Chief Operating Officer of HSC.

The Review Committee recommends the further implementation of the Program Management model at HSC through the clear assignment of costs and the generation of performance information along program lines.

The Review Committee recommends that on a cyclical basis, the HSC evaluate the performance of its program teams to ensure that they are functioning on the basis of shared leadership and the full utilization of the disciplinary expertise of all members.

The Review Committee recommends that the HSC examine means to encourage more physicians to participate in courses on teamwork and conflict management. This would involve, in part, examination of alternative remuneration arrangements for physicians.

The Review Committee commends HSC authorities for the creation in January 2001 of the Nursing Practice Council and recommends that the Council become a key source of advice on nursing practice issues throughout the institution.

The Review Committee recommends that the leadership of HSC give serious and sustained attention to changing the climate and culture of the institution as a more prominent part of an integrated strategy for organizational change.

The Review Committee recommends that part of the cultural change process within HSC involve a recognition of the inevitability of medical errors and other untoward events and an acceptance of the need to learn from such developments.

The Review Committee was impressed with the new critical incident reporting policy within HSC. We recommend that the policy be strengthened by including protection against reprisal for individuals who raise legitimate, reasonably-based concerns.

The Review Committee believes that the current structure for quality assurance within HSC – which combines line responsibility with corporate promotion and monitoring – offers the best potential for ensuring quality concerns are integrated into everyday decision-making. The Review Committee recommends that the HSC, working with the appropriate WRHA staff, develop a multi-year cycle of quality audits of specific clinical and support service areas.

The Review Committee supports and recommends funding for the proposed Child Health Program Quality Initiative.

The Review Committee believes that the elements of a sound risk management system exist at HSC. The Review Committee recommends that stronger risk management strategies and better information on different types risk be developed.

The Review Committee recommends that HSC authorities explore ways to make the patient experience less intimidating and more supportive.

The Review Committee recommends that the Patients' Representative Office at HSC should be more visible, should act as a neutral intermediary between patients and hospital personnel, should track patient complaints over time, and should report directly to the Vice-President and Chief Nursing Officer.

The Review Committee recommends that the accountability of the Chief Operating Officer of HSC to the WRHA Board of Directors be reviewed to ensure that the Board is setting broad policy direction for the hospital and is providing sufficient scrutiny of hospital operations to assure itself that competent, safe, effective and ethical care is being provided.

Chapter 5

The Issue of Informed Consent

Introduction

The Sinclair Report concludes that the parents of the children involved in the 12 cases were not as fully informed as they were entitled to be when asked to give consent to surgery on their children.

Nearly 10 pages near the beginning of the Sinclair Report are devoted to the legal requirements of informed consent and the report comments critically on a number of errors or deficiencies in communication with the parents at different stages in the operation of the pediatric cardiac surgery program at HSC in 1994.

The Sinclair Report recommends three levels of response to the serious issue of informed consent:

First, it recommends that Manitoba Health prepare a patient's rights handbook that, among other things, deals with the issue of informed consent.

Second, it recommends that Manitoba Health direct hospitals to provide, as part of the informed consent process, information on the experience of the surgeon performing a particular procedure as well as the experience of the hospital and/or the surgical team.

Third, it recommends that the HSC review its policies on consent and communication so that medical staff are required to be forthright and truthful in disclosing all relevant information to a patient or their designate.

Although it is not formulated in a precise manner, the Sinclair Report seems to be calling for information to be provided on a number of levels in order to promote a broad concept of informed consent.

LEVELS OF INFORMED CONSENT

The first level of information provision would involve easy public access to comparative information about the education, experience and practice record, including disciplinary actions, for individual physicians and surgeons in different fields. Such information is often described as "physician profiles" or "physician report cards." If made widely available through pamphlets or on-line, such profiles would enable health care users to make better informed choices about which physician or surgeon they wished to use. Publication of information about the preparation and practice of doctors, including whether they had encountered problems in their practice, would supposedly provide an incentive for them to upgrade their knowledge/skills and professional conduct. Over time, the quality of medical practice would improve as a result. The issue of physician profiles and whether they will work as intended to both maintain and improve the performance of doctors individually and collectively is left to a later section of this report where the role of the College of Physicians and Surgeons of Manitoba is discussed.

A related type of information provision involves the publication of comparative evidence on the performance outcomes of individual doctors, surgeons and surgical teams and of hospitals. Once again, the assumption is that patients must have ready access to such information if they are to use the health care system intelligently, including decisions about by who and where they would like to have their surgery performed. The generation, compilation, analysis and interpretation of outcomes data is still at a very preliminary stage in most fields of medical practice. There is controversy over what outcomes should be measured and how, whether and how outcomes should be attributed to individual physicians, and how outcomes data should be interpreted and utilized. Some researchers argue persuasively that a focus on a limited number of **outcome** measures, like death or complications, will yield far less useful information in terms of improving medical practice than would a focus on the **process** of health care provision, which is tied into a robust quality assurance program. Similar issues surround the development of "hospital report cards" like those which have been under development within the Province of Ontario since 1998 and are in widespread use in the United States. Later in this section of the report we discuss not only the potential of performance reports on physicians and hospitals, but also the significant analytical, financial, institutional and "political" obstacles involved with gaining their adoption and widespread use.

CLARIFYING THE CONCEPT OF INFORMED CONSENT

It is the third level of informed consent involving individual patients agreeing to undergo a particular medical procedure that will be discussed here. At first glance, informed consent seems like a straightforward concept. Upon further examination, it turns out to be a very complicated legal, ethical and psychological, interpersonal process of communication. What constitutes fully informed consent is open to interpretation in particular cases and is therefore controversial. Even reading just the Sinclair Report's interpretation of the legalities of the issue led us to conclude that whether valid, informed consent has been granted, all depends on the circumstances of particular cases. Generalizations are fraught with difficulty.

As a starting point for this discussion, we refer to the definition of informed consent as offered by HSC in its Corporate Policy and Procedure Manual (Date 95/05/31):

> "Informed consent for health care is a process which involves communication, dialogue, understanding, and trust between the patient (or the patient's alternate) and the physician (or other health care provider) whose responsibility it is to carry out the proposed diagnostic, therapeutic or operative procedure."

Consent can be either expressed or implied; it can be verbal or written; it can be qualified or unqualified; and, of course, it can be refused. Having the patient sign the consent form is a familiar and important ritual of medical practice, but the form is simply evidence in written form that the patient confirms that he/she understand the explanations that have been given and agrees with the proposed course of action.

A number of legal principles have come to underpin the concept of informed consent. It is their interpretation and application in complicated factual and sensitive ethical situations where the potential for controversy arises. The five criteria for informed consent identified by Canadian courts are:

- consent must be genuine and voluntary;
- the procedure must be a legal procedure;
- the consent must authorize the particular treatment or care as well as the particular care giver;
- the consenting patient must be competent to consent, i.e. must be legally of age and have the mental capacity to give consent; and
- the consent must be informed.

On the last criterion, information must be provided in language that the patient can understand. The obligation to provide the information rests with the physician who is to carry out the treatment. The information that must be provided includes: the nature of the proposed treatment, anticipated effects, material or significant risks, alternatives available and any information regarding delegation of care. Nurses regularly witness the signing of consent forms, but in doing so they are not testifying to the adequacy of the explanation which the physician gave to the patient.

Informed Refusal

Informed refusal, which is the patient's right to refuse treatment, is part of the informed consent process. If a patient refuses treatment, the physician is legally obligated to advise the individual about the risks of not having treatment. "Waiver" refers to a patient's voluntary request to forego one or more elements of disclosure. For example, a patient may not wish to know all the risks associated with a particular procedure. Because the issue of waiver has not been directly addressed in legislation or common law, its legal status is uncertain. Similar legal uncertainty surrounds the concept of "therapeutic privilege." The term refers to the withholding of information by a physician during the consent process in the belief that disclosure would lead to the harm or suffering of the patient. In some cultures, therapeutic privilege is widely invoked and it is ethically unclear whether patients from those cultures should always be subject to Western standards of consent. However, given the legal uncertainty surrounding both therapeutic privilege and waiver, physicians are advised by their professional associations to avoid invoking the concepts.

Legal and ethical debate also surrounds the issue of what constitutes adequate disclosure of information to provide a basis for informed consent. In Canada, the prevailing standard of disclosure is that of the "reasonable person." Under this concept, the physician must disclose information that a reasonable person in the position of the particular patient would need to know in order to make an informed decision. The courts have also recognized that physicians do not have to disclose information where the patient has prior knowledge, such as the fact pain will accompany post-operative care. The disclosure requirement of informed consent also involves the right of patients to ask questions and the requirement for the physician to respond to questions and requests for further information.

The results of empirical studies suggest that patients' desire for information closely approximates the legal standard for disclosure. In a 1994 study, more than 80 per cent of a sample of surgical patients wanted to know about the nature of the illness, the reasons for surgery, the nature of the operation, the expected duration of their stay in hospital, the chances of a successful result, the expected time to return to normal activities and any special precautions they would need to take after surgery. Studies have indicated that 6–18 per cent of patients prefer not to know the risk of treatment. Most studies have found that routine verbal communication is not completely effective whereas written or combined written and verbal communication can improve patients' knowledge.

TRENDS IN THE MATTER OF INFORMED CONSENT

Recent court cases and the rise of medical consumerism have broadened the concept of informed consent and increased the requirements for disclosure. This trend is most evident in the United States where there is far more litigation surrounding medical practice. Traditionally, informed consent was typically one-sided: the physician explained the treatment plan and the patient listened before giving his/her assent by signing the consent form. The consent process gradually moved along a continuum to recognize the right of patients to ask questions and to insist upon further information. Increasingly, the consent process is seen to require a dialogue in which the physician not only provides all the information that a reasonable person should know, but also solicits the patient's opinions in reaching a joint decision on treatment. The assumption behind these requirements is that patients are entitled to and are capable of understanding more medical information than was previously assumed and that patients who are better informed and truly take part in decision-making are more likely to follow a physician's recommendations for follow-up care and medications.

Effective communication is critical to the achievement of this higher standard of informed consent and full disclosure. If a physician fosters good communication, it will promote trust and confidence within the patient-physician relationship. When there is a more genuine two-way dialogue the patient will be encouraged to provide personal information and to express his or her values, concerns and goals for treatment. Better communication will increase patient adherence to medical regimens.

Patient-Physician Communication

A full discussion of effective patient-physician communication is not possible here. However, it is evident from the Sinclair Report, from our conversations with the parents and from our review of the literature that there is a real danger that complex procedures explained in medical jargon will not be understood by most patients. Doctors need to work at providing information in plain language at a level appropriate for the particular patient they are dealing with at the time. For specialized surgeries, program officials might prepare pamphlets of key questions that patients could pose to physicians. The use of videotapes of physicians explaining the procedures would allow patients the time to absorb information at their own pace. Another device might be to have a representative from the Office of the Patients' Representative discuss with the patient whether the explanation provided by the physician was fully understood and whether they have any lingering concerns or questions. These ideas are not novel and are already in use in some programs. We mention them to reinforce the point that consent must be voluntary, informed and based on the best understanding possible in each case.

It appears that many physicians do not meet the more challenging standard of informed consent which is emerging through court cases. A study published in the Journal of the American Medical Association in December, 1999 looked at more than 1,000 patient encounters with internists, family practitioners, general surgeons and orthopods. Fewer than 10 per cent of the clinical decisions reviewed met with the authors' standard for informed decision-making. Few of the physicians bothered to discuss treatment alternatives or tried to learn whether the patients understood the clinical decisions affecting them. We recognize that these findings involve one study conducted in the context of the medical system in the United States. However, we suspect that Canadian physicians, particularly those who completed their medical education sometime ago, may not be as aware of, or as fully compliant with, the stricter legal requirements for informed consent as they should be.

Medical Education and Consent

The Medical Council of Canada has prepared a useful document on the Considerations of the Legal, Ethical and Organizational Aspects of Medicine (CLEO), which contains material on informed consent. Legal and ethical issues appear to be receiving more attention within the curricula of medical schools. Still, given the direction of recent court rulings and the pressures from health consumers for more involvement in their own medical care, physicians and health institutions would be well advised to review their policies, practices and individual approaches to meeting all the requirements for informed consent.

We recognize that physicians are busy professionals and that a fee-for-service model for remuneration provides an incentive to increase the number of patients they see and the number of procedures they conduct. These facts may at times get in the way of an appropriate informed consent process. Given the growing risks to their professional reputations and practices faced by doctors, they need to revisit the issue of informed consent on a regular basis. In the case of surgeons performing low volume, high-risk surgeries (like those in the pediatric cardiac surgery program at HSC back in 1994) specialized consent procedures

may be needed. Also, to avoid both the reality and the appearance of performing too many or too high-risk surgeries as the way to maintain their incomes, surgeons in such programs could be employed on the basis of a flat fee contract, regardless of how many operations were performed in a year. We have more to say elsewhere in this report on alternative remuneration models and the incentives they produce for different types of physician behaviour.

INFORMED CONSENT AT HSC

Since 1995 the Health Sciences Centre has been undertaking a continuing review of its policies and practices governing informed consent. We have reviewed the section of its Corporate Policy and Procedure Manual dealing with the topic and have spoken with the relevant hospital authorities on the evolution of this policy. We have also reviewed the variety of forms used to obtain informed consent, informed refusal, the authorized use of delegates and a number of other types of consent. A signed form doesn't necessarily mean that a patient has been fully informed. Nor is it a substitute for a meaningful discussion between the patient and the physician. A strength of the HSC policy is its emphasis on consent as a process involving communication. As with all policies, the challenge is to ensure that it becomes a guide for behaviour. Ongoing education, communication and debate on the topic of informed consent should become the pattern at HSC. Based upon what we have seen, the HSC consent policy and its accompanying forms incorporates the main features of similar processes elsewhere. We would recommend that HSC authorities investigate the changes to the policies, practices and forms governing informed consent that were introduced in the aftermath of the Bristol Inquiry, a similar tragic set of events involving infant deaths in a pediatric cardiac surgery program.

There is an opportunity for HSC to become a "role model" for other health institutions in terms of developing a "state-of-the-art" set of policies and practices around informed consent. With the leadership and guidance of the Winnipeg Regional Health Authority, the model developed at HSC could be adopted elsewhere to ensure relative uniformity and consistency in the approach to achieving informed consent at the various health institutions. While we did not have the time to investigate the matter in depth, it is our impression that, apart from core features, there is considerable variation in how the consent process operates in different locations. Some flexibility in approaching how informed consent is sought is obviously necessary given the variations in size, staff levels, case mix, specializations, etc. found in Manitoba's hospitals, but the promotion of a more consistent approach is desirable.

DISCLOSURE OF PHYSICIAN BACKGROUNDS AND EXPERIENCE

To this point, the discussion has focused on informed consent and the requirements for disclosure of the nature, risks, alternatives and consequences of a proposed medical procedure. Recently courts in the United States and to a lesser extent in Canada, have upheld a variety of informed consent claims that compel physicians to disclose their lack of experience with a particular procedure, the existence of less risky treatment

options, the availability of more qualified physicians and even personal problems such as substance abuse. The Sinclair Report reflects these recent developments that require surgeons and hospitals to disclose more of their performance record with particular procedures. The Report suggests that access to such information should become a "right" which would be set forth in a "Patients' Rights Handbook" produced by Manitoba Health. The handbook would become the basis for a directive to all Manitoba hospitals that they have a "positive obligation" to disclose information about the performance record of individual physicians and surgical teams undertaking particular medical procedures.

However intuitively appealing the idea of "patients rights" might be, implementation of the concept involves a number of difficult issues and trade-offs that are reflected in countries that have actual experience with the idea. We do not claim that the following discussion is exhaustive of the potential benefits and the problems of applying "rights language" to the field of health. The subject deserves more investigation and discussion than has been possible during the preparation of this report. There is the danger that the codification of rights creates expectations and demands within society which will be difficult to meet within the budgetary constraints of today's health care system. Also, if patients have "rights," do they also not have "responsibilities" in terms of lifestyle choices and use of the health system in a responsible manner? We have more to say later in this chapter about the practical issues involved with the creation of various types of health care rights.

Relating back to the previous discussion of the physician's role in the informed consent process, the Sinclair Report includes in its summary of the legal principles dealing with consent that: "A surgeon's inexperience can be a factor affecting risk that a doctor must disclose to a patient" (p.16). It is well accepted that if a patient asks a surgeon about his/her qualifications and experience regarding a particular procedure, there is a duty to answer honestly. However, it is unclear to the non-legal authors of this report whether physicians and surgeons have a legal obligation to volunteer such information if they are not asked directly by the patient. An active offer of information on surgical outcomes does not appear to us to be a legal requirement of informed consent at this time. The Sinclair Report uses the phrase "positive obligation" to describe the responsibility of physicians to provide information about their experience, outcomes and any disciplinary problems involved with the performance of a particular procedure. If doctors are not legally obligated to tell patients these things, are patients not ethically entitled to know whether doctors are qualified to do what they propose? Surgical "success" seems to be statistically correlated with the number of times and the relative frequency with which a surgeon performs a particular procedure. Therefore, with high-risk, low volume procedures like those involved in pediatric cardiac surgeries performed at the HSC in 1994, there could be extra onus on the surgeons to review their experience with patients or parents as part of the informed consent process.

The notion of doctors discussing their own experience with a new procedure is hardly new. If asked, most doctors honestly answer such questions. There is concern, however, when this becomes a "right" subject, to court ruling on whether the right has been fulfilled. Recent malpractice cases in the United States have ruled against surgeons for overstating the number of times they had performed a procedure, failing to reveal complication rates, underestimating the risks involved and failing to raise the option of referral to a more experienced surgeon. Lying about one's credentials and qualifications is clearly misconduct, but this is different from a legal requirement that doctors are obliged to inform all patients about their training and experience.

Disciplinary Histories of Physicians

As part of this broader disclosure requirement, should doctors be obliged to discuss their disciplinary history including any malpractice suits filed against them? Wouldn't a reasonable patient about to undergo a high-risk procedure want to know whether the surgeon had been disciplined or found negligent for injuring another patient while performing that procedure? These issues also arise in connection with the proposal to publish "physician profiles," which is discussed in the section of this report dealing with the College of Physicians and Surgeons of Manitoba. Some of the information on the history of a physician's practice is already available if a patient is sophisticated enough to know where to look and has the time and perseverance to consult a variety of sources. How far back should doctors go in reviewing their disciplinary history? Are they obliged to reveal every unfortunate outcome? Are doctors obliged to disclose every conceivable treatment option and every conceivable risk, no matter how unlikely? How will juries interpret what a "reasonable person" needs to know in connection with these questions? Are there any valid generalizations about these requirements or does it all depend on the circumstances of individual cases?

The issues become even more complicated when courts consider whether doctors are obliged to inform patients of personal factors which might affect treatment, such as alcohol abuse or marriage breakdown. The matter of financial incentives for doing or not doing a particular procedure has also been raised in malpractice cases when lawyers for plaintiffs have alleged conflict between the interests of the patient and those of the physician.

The trend towards broader disclosure requirements has been strongest in the United States. Compared to Americans, Canadians have never used the courts as much to challenge physicians' judgements and actions, but the gap between the two countries may be narrowing. In the eyes of doctors, especially those performing high-risk surgeries, the process of informed consent is becoming something of a legal minefield. A shift is occurring away from a doctor-based standard to a patient-based standard of informed consent and there needs to be a wider public debate, outside of the court process of malpractice suits, about what is a reasonable expectation in terms of disclosure of the different types of information discussed above.

Measuring and Reporting on the Outcomes of Surgeons and Programs

As part of the proposed patients' rights handbook, it is recommended that there be public access to information on "the experience of the hospital and/or the surgical team" in performing a particular procedure. This right is to be linked to a right to a second opinion and the right to choose a different surgeon or institution, including outside of Manitoba "in certain circumstances." We will address the issues of second opinions and out-of-province referrals in a moment. Here we will focus on the proposed requirement that information be provided on "the experience" of the hospital and the surgical team.

Where this recommendation appears in the Sinclair Report (p. 481), it is not entirely clear what kinds of information or experience is being sought. The recommendation appears in the context of a discussion of

the requirements for informed consent and the reader might conclude that what is sought is seemingly straightforward information on how many times a particular procedure has been attempted with what rate of success. Upon further examination and reflection, however, this call for basic information is not as simple as appears at first glance, as is discussed below. To further complicate the issue, the Sinclair Report recommends elsewhere (p. 498) that the HSC develop an appropriate database for all surgical procedures, especially for pediatric cardiac surgical operations. The contents of such a database will be discussed later. It is suggested that the availability of such a surgical database would allow for appropriate monitoring of surgical trends and provide early warning signals if surgeons and surgical teams were experiencing problems.

In addition to some imprecision in these recommendations, there are a number of potential problems involved with putting them into practice. The recommendations involve the complicated and controversial theory and practice of performance measurement in the health care field. There are conceptual, analytical, technical, financial, institutional and "political" issues involved with the generation, publication and utilization of performance information in the health care system. There is not the space here to present a comprehensive review of these issues. But it is important for us to indicate the potential benefits and problems involved.

Performance Measurement

To measure performance one needs to know what performance is. As banal as this statement sounds, it raises an important conceptual and analytical issue involved with measuring and improving health care. Performance refers to the process of producing and delivering health care services. It also refers to the impact of particular medical and other health interventions on individuals, groups within the population and society at large. Performance is usually said to involve combining **inputs** (authority, money, personnel, etc.) to produce **outputs** (products, services, activities, etc.) to achieve pre-determined **outcomes** (impacts or consequences for people and society). Significant progress has been made in measuring and controlling inputs and outputs, but serious conceptual and analytical challenges arise in measuring and validly attributing outcomes to the programs under examination. Identifying the relative importance of numerous factors – such as, the severity of the illness, the diagnostic skills of the physician, the quality of the institutional facilities, the compliance of the patient with medical advice, etc. – is a difficult analytical and technical challenge.

The growing use of performance measurement in the health field involves a number of assumptions that:

- unambiguous standards of quality care can be identified;
- inputs, outputs and outcomes can be measured;
- the generation and use of measures will lead to quality improvements; and
- activities are repetitive and comparisons among providers and over time are possible.

Understood in this way, there is an appearance of scientific, objectivity to performance measurement. However, in practice performance measurement remains an inherently subjective, value-laden and therefore

controversial activity. Why measurement takes place, what gets measured, how it is measured, who interprets findings and how they are interpreted and what happens as a result, are all debatable issues at this point in the development of performance measurement in the health field.

OUTCOMES MEASURES

The shift to a greater reliance upon outcome measures to gauge provider performance and to promote quality care is a relatively recent development. Traditionally, quality care was equated with professional self-regulation and the existence of professional standards. Two decades ago, A. Donabedian, The Definition of Quality and Approaches to Its Assessment (1980) introduced the conceptual framework of structure, process and outcome to support quality assurance activities. At first, structural measures (eg. organizational design, personnel, adequacy of facilities, etc.) and process measures (eg. adequacy of clinical procedures) provided the basis for performance assessment. The logic was that if structure and process standards were met, high-quality care and outcomes would result. It was also assumed that physicians and surgeons were competent and committed to ongoing professional development. However, the link between structure and process factors and patient outcomes was found not to be always clear. Adherence to standards does not always guarantee good results. This realization, combined with the rise of the quality improvement perspective in health care, encouraged the development of outcome-based performance measures.

There are multiple aims of outcomes measurement in the health field:

- determine the impacts of medical activities on individual lives;
- promote improvement;
- monitor provider performance;
- compare doctors and programs;
- allocate resources;
- ensure accountability; and
- enable better informed patient choices.

It is doubtful whether a single performance measurement system can serve all these aims equally well and people will disagree over which aim is more important. For example, physicians tend to adopt a "clinical perspective," which emphasizes the accuracy and efficacy of diagnosis and treatment. Health care administrators tend to adopt a "system perspective," which focuses on efficiency and accountability.

MEASURES AND INDICATORS

Reflecting the multiple aims of performance measurement, multiple measures and indicators have been developed over time within the health field. Traditionally, health outcome measurement has focused on mortality and related issues like preventable deaths. More recently, there has been increased attention to morbidity and health-related quality of life (the individual's life subsequent to a specific health care inter-

vention). Length of hospital stay, readmission rates to hospitals, and patient satisfaction surveys are other popular forms of outcome measurement. All measures, even those which are seemingly the most "factual" and "objective" are profoundly affected by the circumstances in which the health intervention takes place.

Often the terms "measures" and "indicators" are used loosely and synonymously in the field of health measurement. Technically, a measure is a more direct and precise statement of what has occurred as a result of a health intervention. An indicator is less precise; it represents more of a proxy for direct measurement. In practice, however, both measures and indicators seldom provide completely unambiguous evidence on why specific outcomes have occurred. Most outcomes evidence represents "dumb data," which does not speak for itself and must be interpreted. As a result there can be controversy over the significance of a negative finding and over what needs to be done to improve performance.

An example of this point is the continuing debate over the relationship between the **processes** and the **outcomes** of medical practice. The generation, analysis, utilization and publication of outcomes data for physicians and surgeons and for programs and entire hospitals would supposedly support a number of aims; such as promoting quality care, dealing with problem doctors, providing an early warning that programs are in trouble, enabling better informed patient decision-making and strengthening accountability.

While there has been a trend towards outcome measurement, some experts insist that process measures offer several advantages over outcomes in terms of improving medical practice. Critics of outcomes measurement point to the difficulty of developing valid and fair measures because of such complicating factors as the severity of the illness, a low volume of cases with limited statistical power, the need to adjust for varying levels of risk associated with different case mixes, referral and selection biases, the degree of patient compliance with medical advice and the potential for physicians and institutions to achieve more positive "scores" through their decisions about who to treat and how to treat them. In comparison to these problems, process measures are said to offer a number of advantages: less need to control for the severity of illness, less need to stratify patient populations for risk, fewer incentives for doctors and institutions to "play games" to achieve higher scores and less danger of invalid, unfair and damaging comparisons of the performance records of doctors and institutions. More readily than outcomes measures, process assessments can identify areas for quality improvement and, despite some limits, they can also shed some useful light on the quality of medical judgement of individual doctors.

Ideally, of course, measures should be available for all three parts of the Donabedian triad-structures, processes and outcomes – as part of an overall quality assurance framework. In practice, however, there are resource limits to what can be measured. Information is not a free resource and the development of a comprehensive, valid and rigorous performance measurement system is expensive in terms of funds, information technology, trained staff and time. All of these resources are in short supply within Manitoba's hospitals today.

There is a serious dilemma here for health policy-makers. Evidence-based decision-making should be the basis for improvements and the public wants the assurance that programs are high-quality and safe. Yet most health institutions are currently not organizationally ready to undertake sophisticated performance measurement on all their activities. To force these institutions to collect and publish complex data in the absence of adequate facilities and skills would lead to a focus on the most obvious indicators (like death) and/or would reduce the validity of the data for decision-making purposes.

Studies of the experience with performance measurement and information management in various organizations, including health care organizations, suggest that the ideal of scientific and rational decision-making based upon objective evidence is not upheld in practice. Power, politics and economics play a key role in how information is gathered and used. Reliance upon evidence to guide decisions is also affected by an organization's culture and climate – matters which are discussed elsewhere in this report. What is often found in existing computer systems is dated information with little or no context or clues to meaning; information which is not derived from robust causal models of how program interventions cause outcomes; and information in such enormous volumes that no one has the time to analyze it in a timely, systematic and indepth manner. These realities provide much of the explanation for the depressing finding that a great deal of performance evidence gathered at significant expense is simply not utilized to guide decisions.

Therefore, in the health field, before we take scarce dollars away from direct programs spending to improve health, we must pay careful attention to the relevance and potential for utilization of performance data. Also, attention must be paid to the relative cost-effectiveness of spending on different areas of performance measurement in health. Choices will have to be made on the level and types of measures and indicators to be developed throughout the Manitoba health care system. The Sinclair Report called for the development of databases for all surgical programs at HSC, particularly for the pediatric cardiac surgery program. There has not been a pediatric cardiac surgery program in operation at HSC since 1994 and the Review Committee is recommending elsewhere in this report that for the foreseeable future no such program be initiated within Manitoba alone.

There are major issues and potentially large investments involved with the proposal to develop outcome measures for all surgical procedures at HSC. Although the Review Committee was not able to study carefully the present information management system at HSC, we suspect that it generates basic tracking information on patients, activity levels in different areas and financial information. In these respects, it probably resembles the information management capabilities of most Canadian hospitals. It is not clear from our discussions with HSC authorities the extent to which the transition to a program management structure has been supported by an integrated performance information system which brings together clinical, administrative and patient satisfaction data on a program basis. We suspect there is a lot more progress needed on this front, but we also do not underestimate the obstacles and the costs involved.

To achieve intelligent investments in information infrastructures there will need to be stakeholder consultations, planning and choices within the context of limited resources. There are issues of whether health databases are best developed at the national, provincial, regional or facility level. Within institutions like the WRHA and HSC the leadership will have to decide whether information investments will be spent first on low volume, high-risk surgical procedures on the assumption that is where poor outcomes are most likely to arise. Or alternatively, it might be argued that high volume, more routine procedures should be candidates for outcomes monitoring because they represent the majority of the activity at an institution and affect the largest number of patients.

In the United Kingdom, cardiac surgery has been a leading area for the measurement of outcomes. Since 1977, the Society of Cardiothoracic Surgeons has collected activity and mortality data on all cardiac surgical procedures performed in each National Health Service (NHS) cardiac surgical unit, amounting to 35,000

procedures a year. Similarly, the UK heart valve registry has collected national valve surgery data since 1986. Up until 1994, the data in both registries was for units, not individual surgeons. It was recognized that unit figures could hide poor performance by individual surgeons. So in 1994, the Society established a national database, to run parallel with the existing registry. The database collects some 150 datapoints on all adults undergoing cardiac surgery in about half of all units across Britain. The data does not at present, identify surgeons since this would have been an insurmountable obstacle to launching the project back in 1994. However, the Society requested in 1997 that all NHS units retain annual raw surgeon specific mortality data for adult cardiac, thoracic and pediatric cardiac surgery, as an extension to the existing register. These data will be analyzed and scrutinized within the Society. Individual surgeons will be notified and required to respond if their performance appears to be outside of predetermined standards. According to the Society, this monitoring system will provide a specialty-based, early warning system at little additional cost to the hospitals involved. The Society is also involved in a partnership with the European Association for Cardiothoracic Surgery and the Society of Thoracic Surgeons in the United States to develop an international cardiac surgical database. This arrangement will facilitate data development and risk modeling among populations, procedures, institutions and surgical teams.

We mention these developments in the UK to indicate what is possible and that progress is being made through the leadership of the specialists in the cardiac field. There remain complex and sensitive issues to be addressed. Premature insistence upon the publication of outcomes data could be unfair and damaging to surgeons and units if account is not taken of all the factors involved. Attributing mortality rates to individual surgeons could ignore the subtle but important role of prior disease management, the role played by other professionals on the surgical team and the quality of post-operative care. Simultaneously tracking and publishing outcomes data for individual surgeons and surgical units could lead to divisions among health professionals when "bad news" has to be reported. The result could be an undermining of the team approach which is central to the program management model. Within surgical teams there might be a temptation to camouflage mistakes rather than to learn from them. We offer these cautionary observations not to kill a good idea, but to remind decision-makers that there are different values and interests involved which need to be reconciled in embarking on moves towards more widespread use of performance measurement in the health field.

The Right to a Second Opinion

The Sinclair Report calls for the recognition of the right of patients to have a second opinion. This right would be contained in the Patients' Rights Handbook and would be the subject of a directive from Manitoba Health to all hospitals requiring them to communicate this right to patients as part of the process of obtaining informed consent.

Most Manitobans probably believe that they already have the right to a second opinion. In principle, the right to a second opinion seems straightforward. In practice, obtaining the right can be problematic in certain circumstances. There is nothing in law currently which establishes the right to a second opinion. The Code of Conduct of the College of Physicians and Surgeons of Manitoba states that physicians must respect

the right of patients to obtain a second opinion. However, compliance with the Code is voluntary. Also, the Code provides that no physician is obliged to provide a second opinion when asked. If a request is refused, a reason for failing to give a second opinion must be provided.

There are several reasons why the right to a second opinion is less unconditional than most people presume. Circumstances will vary whether the second opinion is being sought from a general practitioner (GP) to another GP, from a GP to a specialist, or perhaps from one surgeon to another surgeon. Most GPs will readily accede to the request of a patient for a second opinion, unless there is a concern that a patient is "doctor shopping." Providing too many second opinions may attract the attention of the Medical Review Committee, which monitors physicians' billings. Referral to a specialist may pose problems if the number in a particular field is small, the waiting lists are long and the risks to patient health might grow with delay. In some cases, a request for a second opinion will require an out-of-province referral and specialists may be reluctant to impose additional volumes of cases on busy professional colleagues in other jurisdictions. Finally, but probably most importantly, beyond a certain point of communication and explanation with the patient, the physician may conclude that there is a breakdown of trust and confidence within the patient-physician relationship and advise the patient to consult another providers.

There will always be individual doctors who consider it an affront to their professional knowledge and reputation to have patients request a second opinion. The extent of this as a problem which stands in the way of patients seeking alternative medical advice is difficult to measure. The Review Committee concludes that the "official endorsement" by Manitoba Health of the right to a second opinion would have some, not easily measured, impact on both patient and physician behaviour. It would give some patients more confidence to question the judgement of their doctors. A small minority of patients might abuse the right by looking for third and fourth opinions. Most doctors would accept that patients are entitled to alternative advice, but a minority would see the entrenchment of the right in government policy as a symbolic vote of non-confidence in their professional competence. Should the Government of Manitoba decide to proceed with the idea of a handbook of patients rights, it should be made clear that the right to a second opinion is not an unqualified right.

THE RIGHT TO AN OUT-OF-PROVINCE REFERRAL AND TO THE USE OF AN OUT-OF-PROVINCE SURGEON

The Sinclair Report is critical of the fact that the 12 families were not informed of the poor record of the pediatric surgery program at HSC and of the option to have the surgery performed in programs elsewhere. More than one family said they were talked out of taking their child elsewhere. In light of these findings, the identification of a right of referral out-of-province and the right to bring an outside surgeon to Manitoba makes some sense. All pediatric cardiac surgery patients have been referred to other provinces since 1995. If the Western Pediatric Cardiac Surgery Network becomes operational, the movement of parents and children to out-of-province locations will become a routine, institutionalized part of health care delivery in this province. We discuss the implications and requirements for that arrangement in a later section of this report.

The Sinclair Report does not limit the right to out-of-province surgery or the use of an outside surgeon to any particular surgical programs, so we must conclude he meant the right to apply to all programs. The report does suggest that the right of out-of-province referral be available "in certain circumstances including where the patient or parent chooses to have a procedure performed by a surgeon or institution with more appropriate experience and where the surgeon or institution in Manitoba lacks the same experience." (Sinclair Report, p. 481) A number of questions arise from this recommendation.

What are the other circumstances in which an out-of-province referral should be allowed? The Sinclair Report is silent on this question. There are some existing policies and practices within Manitoba Health regarding financial support for out-of-province medical treatment and these documents may provide criteria for decision-making on requests for surgical procedures outside of Manitoba.

What happens if the patient's judgement about the superiority of an outside surgeon or institution clashes with the judgement of local officials at a hospital, within the Regional Health Authority and/or within Manitoba Health? How will patients inform themselves on the comparative experience and success rates of outside surgeons and institutions in performing particular procedures? If the Sinclair Report's recommendations for physician profiles and outcomes reports were put into practice, patients might have information about Manitoba surgeons and units but comparable information for out-of-province programs might not be available. Recognizing this right, depending upon how it is defined and qualified in practice, could have significant budgetary implications.

If the out-of-province option was used extensively by patients in connection with low-volume, high-risk surgical procedure, there is a risk that the sustainability of a program might be threatened. As mentioned in our chapter on the recruitment and retention of physicians, surgeons want a sufficient volume of cases to refine and maintain their surgical skills. Beginning surgeons may have difficulty building up their experience and skills if patients opt for out-of-province surgery. We do not know the likelihood of these potential problems, but they need to be part of the consideration of this issue.

Importing outside surgeons to conduct procedures here raises even more serious problems. Given what is said elsewhere in the Sinclair Report about the importance of teamwork to successful surgical outcomes, the idea of bringing doctors in periodically, assuming they were willing to come, seems to present a real risk to the quality of care provided. Part of the diagnosis of what went wrong at HSC in 1994 was the failure of the surgical team to conduct "dress rehearsals" of delicate surgeries, so that all members of the team would be very familiar with the facilities, equipment, surgical techniques and delegation of responsibility. Continuity and shared experience seems to be crucial to high-risk surgery. There are also the practical issues of granting out-of-province doctors licenses and hospital privileges, arranging schedules and settling remuneration matters. We understand that the first choice of most patients would be to receive high-quality medical care close to home and their networks of support. However, this will not always be possible in terms of the size of the patient population, physician supply and the financial resources available in a province like Manitoba. The Review Committee recommends that the decision to use an out-of-province surgeon be the exception and that the decision be based primarily on quality of care considerations, not on the preferences of patients or the willingness of outside surgeons to operate here.

SOME THOUGHTS ON PATIENTS' RIGHTS

Talk of patients' rights has increased in recent years and the Sinclair Report reflects and reinforces this trend by proposing a Handbook of patient rights. Such proposals reflect a number of developments:

- declining deference towards physicians;
- a growing insistence that the self-regulation process for all health professionals protects patients' interests more effectively, is more transparent, and leads to more accountability;
- the proliferation of patient advocacy groups and the adoption of consumer language and approaches in the health field; and
- the demonstration effect of developments in other countries.

Proposals for the introduction of patient rights documents have to be examined in the context of the wider changes taking place in the health care system.

Probably the most relevant example of how the rights concept might work in practice is the experience with the Patients' Charter adopted by the U.K. government in 1991. The Patients' Charter was one of over 40 such citizen charters setting forth rights and standards for public services. Table 1 summarizes the key rights and standards set forth in the Patients' Charter. Another feature of the Charter program is the publication of hospital report cards using 59 indicators. All hospitals are compared annually in published "league tables." In short, the Patients' Charter informs patients of their rights and provides them with comparative information on waiting times, types of operations and other dimensions of hospital performance.

Table 1
Extract of Patient's Charter rights and standards

RIGHTS	STANDARDS
To receive health care on the basis of your clinical need, not your ability to pay, your lifestyle or any other factor	Patients will be given a specific appointment time and be seen within 30 minutes of that time
To be registered with a GP and to be able to change your GP easily and quickly if you want to	There should be a named, qualified nurse, midwife or health visitor responsible for each patient's care. Patients can expect all staff to wear name badges
To be referred to a consultant acceptable to you, when your GP thinks it is necessary, and to be referred for a second opinion if you and your GP agree this is desirable	Operations should not be cancelled on the day patients are due to arrive in hospital. If, exceptionally, an operation has to be postponed the patient will be admitted to hospital within one month of the date of the cancelled operation
To have any proposed treatment, including any risks involved in that treatment, and any alternatives, clearly explained to you before you decide whether to agree to it	Before discharge from hospital a decision should be made about any continuing health or social care needs the patient may have
To be guaranteed admission for treatment by a specific date no later than 18 months from the day when your consultant places you on a waiting list	Patients who are receiving care at home can expect to be consulted about a convenient time and to receive that visit within a two-hour time band, for example, between 2pm and 4pm

A study to assess the impact of the Patients' Charter was conducted in 1997–1998. Evidence was gathered through documents, intensive interviews, focus groups and mailed questionnaires. Patients, doctors, nurses, other caregivers, hospital authorities, National Health Service officials, professional organizations and community-based groups were contacted. Only the highlights of the study can be presented here.

There was found to be confusion about the purpose(s) of the Charter. Was it meant to codify rights, set standards, define the scope of service, support management's role, serve as a symbolic statement of principles and values, or all of these things? Confusion about the purpose of the Charter was blamed on the fact it was imposed from the top-down, without consultation, as a political move which made little difference to how patients used health services. "The overwhelming view of the Patients' Charter among those who had experience of it, was that it had been of limited usefulness," concluded an article based on the study. The benefits of the Charter were:

- to raise awareness among staff of patient needs and rights;
- to help to set standards and priorities for action; and
- to allow for comparisons of performance

In summary, patients felt the existence of the Charter had very little affect on their experience with the health system. This was especially true of less advantaged citizens. Meanwhile, doctors and managers felt that the Charter was a simplistic gesture which raised patient expectations, did not address the real issues of clinical practice, presented artificially precise measures of hospital performance and did not empower members of the public because they had never read or understood the "league tables" buried in the back pages of newspapers once a year.

In the UK, the Labour Government has placed less emphasis on the Charter and has shifted to monitoring outcomes, developing assessment centres for continuing medical education and introducing the concept of physician revalidation on a 10-year cycle. In Canada, the Alberta Government contemplated the introduction of a health charter in 1996 to silence critics who charged the government was destroying medicare with its cuts to health spending. A key purpose of the Charter was to meet complaints about long waiting lists, but the idea was eventually rejected because it took government into the very uncertain and potentially expensive area of rights protection in relation to access and quality of care.

Now that Canadians have had nearly two decades of experience with the Charter of Rights and Freedoms, the proclamation of health rights could create artificially high expectations. The sorts of principles and values enshrined in a health charter could involve more spending obligations for governments than those arising from the Charter of Rights and Freedoms, which provides protection mainly against unreasonable restrictions on individual freedom. The kinds of health guarantees which governments might wish to codify in official documents probably should be seen as widely cherished and respected social and public policy values, but not as fundamental human rights, which are subject to enforcement through the courts. Also, given what is known about the importance of personal lifestyle to good health, any declaration of principles by government should refer not only to patient rights but also to patient responsibilities.

SOME FINAL THOUGHTS ON PROFESSIONAL SELF-REGULATIONS, INFORMED CONSENT, OUTCOMES AND PATIENT RIGHTS

Until the last three decades, it was an unchallenged assumption that health professions, especially physicians, were accountable only to their peers. It was the professional associations who set the objectives and rules that governed performance. It was the profession who defined what was successful performance. The first challenge to professional autonomy came in the form of increased political direction, control and accountability within the health system. More recently, there is a growing insistence on direct input from and accountability to patients and the public at large. The introduction of performance indicators and statements of patients' rights represent challenges to the assumption of many health providers, especially doctors, that only they can define and evaluate competence and successful performance.

The resulting tension can be seen in a relatively recent study in Ireland. In interviews conducted with Irish General Practitioners (GPs) and health managers in 1998, it was discovered that neither group saw themselves as accountable to the citizen-client. The GPs regarded themselves as private contractors and forecast negative consequences if citizen-clients were allowed to dictate how health care was provided. Similarly, senior health managers also did not accept operational accountability to the citizen-client. The researcher who conducted the study concluded that both groups saw performance indicators as serving only narrow accountability goals within the professions and the health care system. Until both groups acknowledge more fully responsibility for their actions to citizen-clients, performance indicators will not be effective as mechanisms of broader accountability to patients and the public. Until health professionals accept more fully the legitimacy of the patient perspective and until more individuals learn to consult and use performance data, the patient-professional relationship will be little affected by the new accountability mechanisms.

RECOMMENDATIONS

The Review Committee commends HSC authorities for their continuing efforts to improve its informed consent policy and to educate employees about its content and requirements. The Review Committee recommends that the informed consent policy at HSC become the model for adoption within RHAs and/or health facilities throughout the Province.

The Review Committee does not support the concept of a Handbook of Patients' Rights for the reasons stated in this chapter. Instead, the Review Committee recommends that Manitoba Health should produce and distribute "A Guide to Manitoba's Health Services." The proposed guide would contain information such as: the principles of the *Canada Health Act*, a listing of the health services which are insured and not insured within the Province, the right of patients to informed consent, the provincial policy on out-of-province travel for medically necessary care, an outline of the delivery structure for health care services and an office location, telephone number and web site where additional information and answers to questions can be found.

The Review Committee recommends that all RHAs and/or facilities produce a similar guide to services and a contact point for questions and complaints.

The Review Committee endorses the development and publication of physician profiles that balance the public's right to know with protection against unfair damage to the reputations of physicians.

The Review Committee endorses performance measurement and performance reporting on surgical and program outcomes. However, it cautions that there are inherent analytical problems with such activities and significant financial costs involved in creating the computer-based information structures required. Manitoba Health should play a lead role in collaborating with other stakeholders in the health system to establish priorities in this area.

The Review Committee recommends that the proposed "Guide to Manitoba's Health Services" indicate clearly that travel out-of-province to receive medically necessary services is not an unqualified right. The Guide should provide a contact location for information on conditions of eligibility and the nature of the financial support for out-of-province travel.

Chapter 6

The Duty of Loyalty Versus the Duty to Inform

Introduction

One of the ethical dilemmas faced by individuals working in the health care field is the potential conflict between loyalty to their employers, colleagues and professional standards versus a duty to protect their patients against incompetent, illegal or unethical behaviour. Such conflicts arise only occasionally, but they are no less challenging in ethical and practical terms for the individuals involved.

There is a continuum of potential responses by individuals as to what they regard as misconduct within organizations. The continuum includes internal protest, active and passive resistance, internal disclosure and external disclosure. "Whistleblowing" represents one form of protest. The concept was first popularized in the United States, where it has become a small growth industry with new laws, procedures, court cases and commentaries proliferating daily. The activity is spreading rapidly to other countries, most of which operate with different constitutional and legal systems and different political traditions and cultures.

Whistleblowing

We define whistleblowing as the unauthorized internal or external disclosure of information concerning a harmful act that a superior or a colleague has committed, is allowing to occur or is contemplating. Disclosing misconduct within an organization is usually less damaging than "leaking" information to outside parties, such as the legislature, the media or interest groups, but both types of action raise the issue of loyalty.

Key characteristics of whistleblowing are dissent, breach of loyalty and accusation. These characteristics make whistleblowing a morally ambiguous action. In addition to violating several societal taboos (such as, not "squealing" on one's colleague and never airing the "dirty laundry" in public), blowing the whistle often puts loyalty to one's colleagues against loyalty to the public and includes the accusation that one's superiors or fellow employees have neglected or abused the public interest.

On the other hand, such actions of individual dissent are seen as an important way to ensure that large bureaucracies are operating in a legal, effective, efficient, responsive, ethical and accountable manner. Studies suggest that whistleblowers pay a high price in terms of their careers and their personal lives. This leads to calls for stronger legal protections for individuals who legitimately and reasonably disclose wrongdoing, and for greater accountability for their organizations and their leaders who retaliate against justified dissent. If these are the benefits of whistleblowing in the public sector, there are also costs. Regardless of how whistleblowing complaints are resolved, there is bound to be some damage to the image and reputation of a government as a whole. There are also costs to the particular public organizations involved, such as the expense and staff time to deal with accusations and the divisions within the organization which may impair its productivity. Costs to government will ultimately end up being costs to taxpayers.

Ideally, organizations should adopt strategies and activities to reduce the need for employees to resort to whistleblowing. A strategy of prevention would include such elements as: improved communication; an interpersonal climate which fosters mutual respect and support; a culture which tolerates dissent and promotes teamwork, learning and continuous improvement; the use of forums and procedures to channel conflict and disagreements in positive directions; and the adoption of codes of conduct.

Even with such measures, there may still be a perceived need for formal protection of whistleblowers against retaliation when they raise matters that eventually prove to be substantively justified. Whistleblowing should be considered only after all other avenues of addressing a problem have been tried. Ideally, the rules and procedures respecting whistleblowing should encourage "good" types of whistleblowing and discourage "bad" types of such activity. Unfortunately, what constitutes positive versus harmful whistleblowing often involves facts in contention and value-laden subjective judgements. In short, owing to the complexity of the activity, whistleblowing is not an activity that lends itself to immutable rules. Not all situations of perceived risk to the public interest justify whistleblowing and not all whistleblowers are driven by purely altruistic motives.

CULTURE OF SILENCE

Turning to the events in the pediatric cardiac surgery program at the HSC, the Sinclair Report observes that:

- the nurses involved made proper and appropriate use of existing channels to voice their concerns, but were not taken seriously (p. 478);
- their concerns were dismissed as stemming from their inability to deal emotionally with the infant deaths (p. 477);
- concerns about medical matters were rejected as not having a proper basis; and
- nurses were never treated as full and equal partners of the surgical team, reflecting their historical subordinate position in the HSC structure (p. 477).

For these reasons, Judge Sinclair concluded that "... the attempted silencing of members of the nursing profession, and the failure to accept the legitimacy of their concerns, meant that serious problems in the pediatric cardiac surgery program were not recognized and addressed in a timely manner." (p. 478)

The problems that arose in the pediatric cardiac surgery at HSC in 1994 seem to be a clear case where some type of whistleblowing protection would have helped the nurses involved to resolve the ethical dilemmas involved with protecting and advocating on behalf of their patients, respecting the values and standards of their profession, maintaining their loyalty to the surgical team and the institution, and avoiding the risks to their own careers and lives. Perhaps no profession faces the complex issues of whistleblowing more directly and dramatically than nurses. This is true for several reasons. They have expertise from education and experience to understand the nature of procedures and why they are undertaken in the delivery of medical care. In hospitals, nurses increasingly work as equal members on the health care team. That same team includes one of the highest status professions – physicians and surgeons. Within the culture of facilities such as the HSC, nurses are perceived as subordinates to physicians and frequently treated in that manner by the medical community. Nurses are employed by the facility and report to managers who for the most part are nurses with advanced education and experience in nursing management. Nurses are accountable to their respective manager, their patients and their professional association for their practice. While nurses are expected to demonstrate respect and loyalty, they are not expected to obey physicians automatically and unquestioningly. Achieving the acceptance of the nurse as a full and respected member of a professional team will require changes to the attitudes of some individual physicians and surgeons, as well as a transformation of the climate and culture of particular medical programs and the institutions in which they are employed. It is recognized that such changes take time, often years, given how deeply entrenched certain attitudes and values have become. We have more to say on the importance of communication, climate, culture and teamwork in other parts of this Report.

Within hospitals, nurses have the most continuous contact with patients and owe a strong duty, both professionally and personally, to protect the patient's welfare. Codes of ethics have been developed for nurses to help them cope with ethical dilemmas when they arise. Codes deal with such values as the promotion of the health and well being of patients, their right to safe, competent and ethical care, confidentiality and accountability – all considerations relevant to nurses deciding whether to blow the whistle. Codes also encourage nurses to support one another when concerns about incompetent, unethical and unsafe care are raised. In the case of the HSC events, the Sinclair Report notes with regret that frustration, fear and a sense of futility led "some nurses to silence themselves" (p. 478). Studies of whistle blowing in other contexts indicate that, more than fear of reprisal, a sense of futility that corrective actions will not be taken is the main reason that people do not speak out when they identify misconduct.

In response to the findings about the role of nurses within the HSC in 1994, the Sinclair Report calls for changes to improve the status and involvement of nurses in institutional decision-making, including the promotion of a culture of teamwork and the development of skills in conflict management. We discuss these reforms later in this Report. These reforms are clearly intended to prevent the need for whistleblowing, especially the release of unauthorized information to outside bodies. The Sinclair Report (pp. 478–79) still sees the need to provide protection for prospective whistleblowers on two levels.

First, within the employing institution of the HSC, the Report recommends that there should be established a clear policy on how employees are to report concerns about risks to patients. Such a policy would clarify to whom each employee is to report; presumably that would be their supervisor or manager in the

first instance. The policy should also make clear that there will be no risk of reprisals for the person raising legitimate and reasonably held concerns. As part of the same group of recommendations, the Report also recommended a strengthened Nursing Council within HSC to serve as "a vehicle through which nurses could report incidents, issues and concerns without risk of professional reprisals" (p. 479).

The above set of recommendations calls for whistleblowing rules and procedures created by individual institutions in the health care field. However, the Sinclair Report also recommends that the Government of Manitoba consider passing whistleblowing legislation of more general application to "protect nurses and other professionals from reprisal resulting from the disclosure of "legitimately and reasonably held concerns" about "the medical treatment of patients" (p. 479).

Like other recommendations in the Sinclair Report, those dealing with disclosure of misconduct may have been overtaken by developments which have occurred since the conclusion of the Inquest. Also, the recommendations are formulated in general terms and any implementation plan would require more detailed, operational issues to be addressed.

In terms of subsequent developments at the HSC, a new Nursing Practice Council was established in January, 2001. It has been described by HSC authorities as "a work in progress" in the sense that its mandate, scope of operation, decision-making authority and influence, and its potential as a forum for reviewing and resolving the concerns of nurses related to patient care, are not entirely clear at this point. A Vice-President of Nursing has also been established as another way, to bring nurses' concerns to the centre of the HSC decision-making process. Voluntary courses on teamwork and conflict management have been offered within the institution. At this point, it is not clear how many physicians and other health professionals will participate in such courses. More is said on these points in other parts of this Report.

To date, the HSC Executive and the WRHA Board (to which the HSC President reports) have not developed a formal policy statement on the duty of employees to report risks to patients. Apart from existing reporting relationships and the critical incidents process, there are not identifiable rules and procedures to guide nurses and others in bringing concerns forward within the institution. Apart from common law, employment law and collective agreements, there are not legal protections for prospective whistleblowers who may fear retaliation.

INTERNAL DISCLOSURE

The development of an internal disclosure procedure is preferable to external whistleblowing, both for the organization and the employee. An internal process gives the organization the opportunity to correct the problem and avoid the investigations and negative publicity that usually accompany external whistleblowing. A properly structured and operated internal disclosure procedure also has a better prospect of allowing ethically concerned employees to identify with the organization and continue their careers within it after they have raised their concerns. The provision of internal disclosure mechanisms is also consistent with the statutory provisions and jurisprudence in some jurisdictions. Such whistleblower laws place the onus on the employee to exhaust internal remedies before taking their concerns outside of the organization.

While internal disclosure programs have much to recommend them, they may not always be the most appropriate way to encourage employees to come forward with information of serious wrong-doing. Unless an organization has established a "secure channel" which ensures complaints will be dealt with confidentially, employees may be reluctant to report matters to their superiors, even if there is an organizational policy offering protection against reprisal. In addition, the idea that problems can be handled internally, may not be appropriate when serious issues, like alleged illegalities or specific dangers to public health, are involved.

Authorities at the HSC and the WRHA have not committed to the development of an internal disclosure policy and procedure. They continue to rely upon existing procedures for reporting concerns–through the chain of command, through the monitoring procedures (critical incident reviews and standards committees), and through the norms of professional behaviour that are reflected in codes of ethics for physicians, nurses and others.

Policy on Internal Disclosure

It was not the task of this Committee to develop a detailed policy for how the HSC should deal with employees' concerns about different kinds of misconduct. However, we believe that such a policy would be of value to the institution and its employees. It could also serve as a model for other institutions throughout the province. Without going into detail, we wish to identify two crucial components of such a policy.

The first would be an educational component designed to create a culture and climate which accepts disclosure and discussion of concerns as a valuable source of individual and organizational learning and improvement. It is understandable that health providers in all fields do not like to have their behaviour and judgements challenged. But there needs to be greater recognition that no one, including physicians and nurses, is infallible and that the expression of concerns does not amount to an accusation.

To create greater acceptance of the legitimacy of disclosure, a number of steps can be taken. A code of conduct can be adopted. It can cover the types of actions that justify disclosure. It can set forth the procedures to be followed and the protections offered. It should also indicate that unjustified allegations can cause damage to individuals and the institution and that irresponsible or malicious use of the process will have consequences. Such a code should be endorsed at the highest level within the organization – which is usually the board level. Education about the code should be part of the orientation for new staff. Employee groups and unions should be involved in the development and ongoing dialogues about what is proper and improper behaviour.

The second component of an internal disclosure policy would deal with the types of behaviour that are reportable, the procedures to be followed and the extent of the protection against reprisal to be provided. Most organizational policies on whistleblowing cover matters like illegal actions, financial malpractice, dangers to health or safety, and cover ups or violations of the code. Employees are first encouraged to follow normal lines of reporting within the organization. However, there is a recognized need to provide another route to raise a concern, such as to the chief executive or another senior officer. Steps are taken to protect the identity of the complainant at least initially. Employees need to be assured that they will be supported

and protected from reprisals. They need to be informed whether there are external routes if they do not have the confidence to raise a concern internally. There should be a guarantee that the results of an investigation and the actions that follow will be reported back to the complainant. Employees should also be informed that raising unfounded allegations maliciously is potentially a matter for disciplinary action.

An internal disclosure policy can serve to galvanize and reinforce existing values of safe, competent, ethical and compassionate care by operating in conjunction with other hospital processes. True responsible behaviour comes about when professional standards and ethical norms are deeply internalized by everyone who works in a hospital. A poorly designed policy and set of procedures could poison the work environment with suspicion, accusations and conflict and could cause stress and damage, both for the individuals who complain and for those who are accused, perhaps unjustly. There are enough working models around to enable the design of a sound policy. There will be costs – staff time, materials, information gathering, etc. – but these need not be great. An internal disclosure process should be seen as a last resort, when existing quality control processes and communications channels do not prove effective.

PROVINCIAL WHISTLEBLOWING LEGISLATION?

The Sinclair Report also recommends whistleblowing legislation to operate system-wide across the health care system "to protect nurses and other professionals from reprisals" resulting from the unauthorized disclosure of information about "legitimately and reasonably-held" concerns over the medical treatment of patients. There is currently no general whistleblowing law in Manitoba whether in relation to public sector employees in general or to health care providers in particular. The *Protection of Persons in Care Act* (PPCA), proclaimed May 1, 2001, has been popularly described as a whistleblower law. The PPCA requires a health care provider or any person who believes that a patient in a hospital or a personal care home is being, or is likely to be, abused to report to the Protection for Persons in Care Office, Manitoba Health, on a mandatory basis. Following an investigation of the report, direction may be provided to the institution, which must comply within a prescribed time by describing what action has been or will be taken. The *Act* itself protects employees from retribution for bringing incidents to the attention of authorities. It also protects employees from malicious reporting.

The PPCA primarily covers incidents of abuse, actual or potential. Other types of disclosures – such as the disclosure of incompetent, illegal, fraudulent or unethical behaviour – typically found in general whistleblower statutes, are dealt with under the PPCA through referral to appropriate professional bodies, law enforcement or other organizations. The PPCA imposes on all employees in health care institutions and the public at large a duty to report, whereas the wording of the Sinclair Report (p. 479) indicates that the proposed law would cover only "health professionals."

It is impossible to discuss here all the issues involved with a general whistleblower law. The examples of the *Whistleblower Protection Act*, 1989 in the United States, and the *Public Interest Disclosure Act*, 1999 in the U.K. are discussed briefly in Appendix E and Appendix F. There are also numerous states that have adopted general whistleblower laws. It is difficult to assess the effectiveness of these laws in terms of causing people to come forward and in offering protection for people who raise legitimate concerns. Accordingly, the fol-

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lowing generalizations about the impacts of whistleblower statutes should be interpreted with some caution:

- the number of cases of individuals seeking protection under state whistleblower laws was comparable to, or less in number, than in states where common law provisions against unjust dismissal and labour agreements are the only protections;
- strongly committed whistleblowers do not appear to engage in rational calculations of the costs and benefits of dissent;
- in the United States, there are relatively few whistleblower cases that actually proceed to court;
- statutes in the United States may have had the beneficial effect of encouraging employers to develop internal disclosure procedures.

In general, available studies suggest that whistleblower statutes have had limited impact because they are not well understood and/or are perceived as ineffective in protecting individuals who use them. Most laws do not provide an incentive for individuals to come forward. For most people, the decision to blow the whistle is seen as a decision to quit one's job and perhaps to short-circuit one's career. In the United States, the protection against wrongful dismissal in common law and in labour relations law proved to be more effective in terms of the damages awarded by courts than the existing whistleblower statutes. In many state statutes, the deadlines for invoking protection are often short, 60 to 90 days, whereas common law suits do not involve such limits. Advocates of whistleblower laws have developed principles of statutory construction to make the protection stronger. But even with such improvements, it will remain a tiny minority of people in any organization who will risk the stigma, hostility, emotional distress, potential loss of income, damage to their careers and disruptions to their personal lives that comes with appearing to be disloyal and betraying one's colleagues.

Having indicated the limits of a legislative approach, it should be recognized that the passage of a whistleblowing law would have a number of potential benefits:

- passage of a law would send the symbolic message that there is a justification for disclosing misconduct if it represents a danger to the public interest;
- it would provide clear, statutory protection for persons who blow the whistle;
- it could allow for reinstatement and punitive damages, not just compensatory damages. Courts have been reluctant to order reinstatement in the case of wrongful dismissal;
- if drafted to protect internal whistleblowing, legislation would encourage employees to raise matters within organizations first and would encourage organizations to develop a confidential internal process;
- a law would provide protection when organizations refuse to adopt voluntarily their own internal disclosure program;
- a law would encourage employees to report misconduct to the appropriate authorities, rather than to the media;

- a properly designed whistleblowing law would help employees who may be uncertain or mistaken about the misconduct they have observed and this could help to avoid the precipitous release of sensitive information and the damage that could ensue.

More generally, the adoption of a whistleblower law would deal with secrecy and promote accountability by encouraging people not to turn a blind eye to misconduct. Through its sanctions, it would help encourage organizations to address the message, not the messenger. It would limit the temptation to cover up serious problems. In the case of the health field, such a law would reflect and reinforce the duty of disclosure of unsafe and unethical practice found in the codes of ethics adopted by health profession organizations.

As the above discussion indicates, there are advantages and disadvantages involved with general whistleblower laws. The most far-reaching whistleblower protection law in the world was adopted in the U.K. in 1998, in part as a response to an inquiry into the deaths of infants in a pediatric cardiac surgery program in Bristol, England. The *Public Interest Disclosure Act* only came into force early in 1999. The key features of the *Act* are described in Appendix F. Experience with the *Act* is obviously limited. Assessment of its impact on encouraging people to disclose wrongdoing and its effectiveness in terms of providing protection will not be possible for a number of years. This experience may be an important source of learning given that the U.K., like Canada, has a cabinet-parliamentary system (and a public health care system).

Adoption of a Whistleblower Law with regulatory enforcement mechanisms would involve some modest, but not insignificant direct cost to government and probably some indirect costs to the institutions which would be obliged to comply with its provisions. Finally, it should be remembered that the Sinclair Report only recommended consideration of the adoption of a whistleblower law.

RECOMMENDATIONS

The Review Committee recommends that HSC and other hospitals in Manitoba develop policies on internal disclosure as part of a broader strategy to promote cultures and climates of openness and creative-problem solving in which individuals can raise legitimate and reasonably-based concerns without fear of reprisal.

The Review Committee recommends that Manitoba Health monitor the development of internal disclosure policies and their operations within hospitals and the experience with whistleblowing laws in other jurisdictions. If after five years, there are continuing problems and complaints involving a lack of responsiveness by hospitals to concerns raised by their staff, Manitoba Health should at that point consider the adoption of a Whistleblower act for the health field or the public sector in general.

Chapter 7

The Office of the Chief Medical Examiner (OCME)

Introduction

The Sinclair Report made a number of findings and presented eight recommendations respecting the role of the OCME as an external monitoring body responsible for reviewing reportable deaths in hospitals to determine the cause of death and whether an autopsy is necessary. One of the aims of an autopsy is to determine whether a death was preventable. It is within the authority of the OCME to call an inquest if there is a perceived trend in terms of deaths within a particular hospital. Inquests are held to investigate problems and to recommend actions to prevent their recurrence, as well as to provide assurance to the public that hospitals and health care providers are providing competent and safe care.

A brief description of the key features of the OCME operation is necessary to provide some context for the presentation and assessment of the Sinclair Report's findings and recommendations. The Office falls within the portfolio of the cabinet minister who serves as Minister of Justice and Attorney General in the Government of Manitoba and the Office reports to the Minister through the Department of Justice. The significance of this arrangement is that health issues involving the OCME must at times be resolved through two ministers and two departments – namely Justice and Health. The OCME operates under the terms of the *Fatality Inquiries Act*. Under the *Act*, only certain types of deaths are investigated by the OCME. These are called "reportable deaths" and they represent about half of the approximately 10,000 deaths which occur annually within the Province of Manitoba. In the case of the death of a child that might be the result of an accident, suicide, homicide or other unnatural cause, an investigation is mandatory. Deaths of children in hospitals are always investigated.

There are three categories of personnel involved with the investigation of reportable deaths. When a reportable death occurs, a Medical Examiner Investigator (MEI) or Medical examiner (ME) attends the scene to gather information on whether the death was natural, accidental, suicidal, homicidal or undetermined. MEIs are usually nurses. Currently the OCME employs six MEIs, all of whom are nurses and all are

based in Winnipeg. The MEI reports the details of the death to a Medical Examiner (ME), who is always a medical doctor. MEs are not employed directly by the OCME; they are fee-for-service doctors who are paid a flat rate for investigating a death. There are approximately 75 doctors across the province who act on an on-call basis for the OCME. During the past year, there has been a fee dispute between the Department of Justice and the Manitoba Medical Association, who represent the MEs. This dispute led to the withdrawal of ME services as of December 22, 2000. In a newspaper report (Winnipeg Free Press) on January 9, 2001, Dr. Thambirajah Balachandra, the Province's Chief Medical Examiner, was quoted as saying that the OCME could fulfill its statutory responsibilities without the services of the MEs. For communities outside the City of Winnipeg the elimination of MEs would create a serious problem, the extent of which has not been determined at this point.

Based upon a report from the ME, an autopsy may be performed to determine the cause of death. Doctors who are trained in pathology carry out autopsies. Currently, the OCME relies on pathologists who work at Health Sciences Centre, St. Boniface General, and other facilities to carry out autopsies. Pathologists do not work directly for the OCME, they are employed by the WRHA or other employers, and the medical-legal work they do for the OCME is in addition to their normal duties. This point becomes significant in the later discussion. Some pathologists specialize in pediatric pathology. A few pathologists have done additional graduate studies to earn the designation of forensic pathologist. The Chief Medical Examiner for the province is always a forensic pathologist.

THE SINCLAIR REPORT'S FINDINGS

Judge Sinclair made several critical findings respecting the role of the OCME back in 1994:

- it did not at that time track deaths by surgical program and was not, as a consequence, able to identify trends in the pediatric cardiac surgery program.
- it was not informed of changes to the program, including the suspension of the program at one point to allow a review to take place.
- OCME representatives (both MEIs and MEs) relied too heavily on the opinions of the surgeons involved when investigating deaths and did not consult sufficiently other members of the surgical team.
- because it gave rise to an appearance of a conflict of interest, it was inappropriate to have autopsies performed by pathologists who worked for the HSC.
- the autopsies of the children whose deaths were under review were not done in a timely manner. This last point requires some expansion to link it to discussions and recommendations found elsewhere in this report.

In Chapter Four of this Report, focusing on the Health Sciences Centre (HSC), the role of Standards Committees as forums for the review of cases in order to deal with deficiencies in performance and to promote learning was discussed. In 1994, all hospitals in Manitoba had a Standards Committee which reported to the Central Standards Committee of the College of Physicians and Surgeons of Manitoba (CPSM). In

the case of the pediatric cardiac surgery program, the deaths were reported to a pediatric death review sub-committee of the HSC Standards Committee (also known as the Centre Wide Standards Committee). A report based upon discussions in the sub-committee would be forwarded to the Pediatric Death Review Committee (PDRC) of the College of Physicians and Surgeons. Testimony to the Inquest revealed that the review of cases at both the sub-committee level within the HSC and at the PDRC level within the CPSM would be delayed until the results of the autopsies were available.

Several crucial points arise from the analysis presented in the Sinclair Report. First, the standards committees process in HSC was not providing systematic and timely reviews of the infant deaths because the process only began when autopsy reports were available. Under the *Fatality Inquiries Act*, autopsy reports are supposed to be completed in 30 days, but often they took several months. Second, the review process conducted by the PDRC of the CPSM did not provide an early detection and timely response mechanism because the PDRC met approximately five or six times a year and only reported publicly on its findings 18 months to two years after the events in question. In summary, the shortcomings of all three organizations – the HSC, the CPSM and OCME – contributed to the lack of an early warning signal that something was seriously wrong with the pediatric surgery program in 1994. While the remainder of this chapter focuses on reforms to the OCME to improve the investigation and autopsy process, there is clearly a need to integrate and coordinate its activities with a wider, interdependent group of organizations.

Judge Sinclair's Recommendations

Judge Sinclair's findings led him to make eight recommendations, each of which will be examined in turn here.

The first recommendation has two parts. The first part is that the OCME develop a protocol requiring hospitals to inform the OCME of "significant changes" to hospital programs and the delivery of medical services. As a basis for improved communication and better coordination within the health care system, this recommendation makes sense. It would not represent a significant administrative burden for hospitals to copy the OCME when notifying other health authorities (like the RHAs and Manitoba Health) of pending program changes.

Having agreed with the principle, the Review Committee is obliged to point out some operational requirements for putting it into practice:

- The OCME does not have the legal authority to order hospitals to notify it of program changes and in practice this is rarely done. To make the requirement work, either Manitoba Health or the RHA involved would have to direct hospitals to comply with the requirement.
- Determining what is a "significant change" to a program that warrants notification of the OCME is not an entirely straightforward judgement and agreement on the operational meaning of the term would have to be worked out in practice over time.
- The recommendation implies that advance notice of program changes would enable the OCME to monitor deaths more effectively. However, more analysis needs to be conducted on how this would occur. Would it involve the reassignment of staff, more intensive investigations, more intensive and timely reporting, etc.?

In summary, the Review committee agrees with the first part of recommendation one, but we believe that it requires more operational clarity before implementation.

The second part of recommendation one suggests that the OCME should be notified of all hospital-related deaths that cause a hospital to undertake a program review. This recommendation reflects the sequence of events in 1994 that caused HSC authorities to suspend the pediatric cardiac surgery program while a review was conducted. If adopted, this recommendation would presumably provide the OCME with a signal that a program was in trouble and, on this basis, it might wish to review existing data or gather additional data on recent outcomes within the program. The Review Committee sees some merit in this recommendation, but raises two practical issues.

First, the OCME has told us that not all hospital deaths are **reportable** to it and that it lacks the resources to investigate all hospital deaths. The responsibility for monitoring in-hospital deaths resides with the hospitals, RHAs and other agencies. Second, both formal and informal program reviews happen regularly in hospitals and, in a significant number of cases, such activity is triggered by a pattern of adverse outcomes including deaths. There would be a need to develop clear rules regarding notification to the OCME respecting program reviews.

The second recommendation is that the OCME develop a database for all in-hospital deaths on a weekly and monthly basis. In 1994, the OCME did not have the staff or technological resources to track reportable deaths. Since January 1, 1999, a Department of Justice Information System has been available and a statistician was hired by the OCME in December 1999 to enter and track data. Since the spring of 2000, the deaths of all children and personal care home residents have been tracked by the OCME on a monthly basis. The OCME has indicated its intention to track these types of deaths on a weekly basis when areas of concern are identified.

Longer term, the OCME indicates its intention to track all reportable surgical deaths by institution, procedure and surgeon. The word reportable is underlined to make the important point that under the *Fatality Inquiries Act*, only certain types of deaths are investigated by the OCME. It is not possible in law or in terms of its current resources for the OCME to track all non-reported, in-hospital deaths. Moreover, the additional resources (mainly additional investigative and support staff) would not represent a cost-effective expenditure since the evidence gathered would not add significantly to the safety and health of Manitobans.

The third recommendation is that MEIs should conduct the initial interviews with medical and nursing personnel. This recommendation was meant to speed up the investigative process. The OCME has informed the Review Committee that this is a reasonable recommendation, but implementation is complicated by staffing shortages and time factors.

Inadequate staffing has been a long-standing complaint from the OCME. The OCME is involved in 5,000 death investigations annually. Depending upon the outcome of the current fee dispute (April 2001) between the Department of Justice and the Manitoba Medical Association on behalf of the MEs, there will be an impact on the future role of the MEIs within the death review process. Currently, the six MEIs all work in Winnipeg. If MEIs were expected to conduct all preliminary investigations across the Province, their numbers would have to be increased significantly.

At present, preliminary investigations can be delayed because the work schedules of the health professionals involved make meetings difficult to arrange. Interviews can be time consuming to conduct and realistically may not be possible until later stages of the investigation. Nursing staff are reluctant at times to meet with the OCME, both because of their concern about sharing protected patient information and about potential damage to their careers. In some circumstances, hospital administrators insist on their lawyer being present and this leads to further delays.

In summary, the recommendation to rely more on MEIs as a way to streamline and expedite the investigation process makes some sense, but it does entail the practical problems described above. The Chief Medical Examiner has indicated that he is taking the opportunity of the current withdrawal of services to assess whether the OCME can function effectively with reduced or no ME services. A final decision on the future role of MEs in the death review process will depend on other changes to that process.

The fourth recommendation was that autopsies not be performed by pathologists affiliated with the hospital where an operation was performed. The concern was that such an arrangement created a perceived conflict of interest. A change since 1994 is that pathologists are no longer employed by HSC, they are now employees of the WRHA. Whether their changed employment status lessens the perceived conflict of interest is difficult to state with certainty since such perceptions inevitably involve subjective judgement on the part of the observer. The pathologists with whom we met insisted that they would always uphold their professional standards and provide the appropriate critical review regardless of who issued their pay cheques. Pathologists are known to be curious, even skeptical, when undertaking autopsies, which is not to say that they are completely free of any reluctance to challenge their professional peers when working within a hospital setting.

The fifth recommendation was that the OCME develop guidelines for pathologists to avoid over-reliance upon the opinion of anyone whose involvement might have contributed to the death of a patient. Information is provided to the pathologist by the MEIs, the MEs, nurses and the physician, as well as from the patient's hospital charts. Further information can be requested as required. While guidelines would be helpful, they would not eliminate the need to provide room for professional discretion and judgement by pathologists in determining whom to contact and what significance to assign to different opinions.

Recommendations six and seven deal with the requirement for timely autopsy reports and the insistence on compliance with deadlines. Currently, under the *Fatality Inquiries Act*, final autopsy reports are supposed to be available within 30 days after the death. According to the OCME, this deadline is very difficult to achieve due to the volume of work and a shortage of pathologists. Pathologists work in the hospitals, where they also perform diagnostic tests for patients who are living. Tests for the living must take precedence over tests on the deceased.

Centralization of Forensic Pathology

Beyond the shortage of pathologists, the OCME insists that the current model of distributing autopsy work among hospital-based pathologists is fundamentally flawed. Reports on autopsies are delayed in reaching the OCME. A better model, according to the OCME, would involve the creation of a centralized facility where most of the work of the OCME would be consolidated. Proposals for the creation of such a

facility have been made to the Government of Manitoba as far back as 1984. The advantages claimed for such a facility and related staffing requirements are several:

- it would allow the OCME to obtain accreditation as a forensic facility;
- it would make pathologists employees of the OCME and allow the Chief Medical Examiner to manage their workloads more efficiently;
- making pathologists employees of the OCME would remove the perceived conflict of interest since they would no longer work in the hospital setting;
- it would provide the OCME with the laboratory space and staff to conduct toxicology tests, an activity which is currently performed at St. Boniface Hospital.

According to the Chief Medical Examiner, centralized systems operating in Edmonton and Calgary should serve as models for Winnipeg.

The Review Committee did not examine the proposal of a centralized forensic facility in depth since a thorough assessment would require more time and analytical capacity than were available to us. Also, the proposal is one that would begin consideration in the Justice department and require endorsement by the Minister of Justice before being brought to the cabinet for a decision. Consideration of any proposal must involve the Department of Health, and the employers of pathologists since the medical-legal component is only one, relatively small part of the role that pathologists play in Manitoba's health system. The proposal has been brought before government several times during the past decade, without a decision to go forward.

In the absence of immediate action on the OCME's proposal to consolidate its operations, we recommend that the OCME conduct a detailed process analysis of the steps involved with its investigations and autopsies to determine whether a "re-engineered process" could maximize staff productivity and expedite the autopsy process. In recommending this step, we are not being critical of the efforts of OCME staff. Re-engineering would be intended to re-design the OCME's processes to reduce the time involved and to enhance productivity. The application of information technology in the process should be examined as part of a re-engineering project. Employees should be involved in the re-engineering process. And finally, the process should balance attention to the "soft" side of the organization (motivation, culture and climate) with attention to the "hard" side of technology and measurement.

The eighth recommendation is that the HSC and other hospitals amend their autopsy consent forms so that families are aware of their right to withhold consent for the hospital to retain organs and specimens. Consent forms are actually the legal responsibility of Manitoba Health and the individual institutions. The OCME reported that it had worked recently with the WRHA to amend autopsy consent forms and to develop guidelines for the retention and the disposal of specimens in both mandatory medicolegal autopsies and in voluntary consent autopsies. The *Fatality Inquiries Act* provides authority to the OCME to retain tissues for evidentiary and diagnostic purposes and, for legal reasons, consent for such action is not required.

The Review Committee endorses the collaboration of the OCME and the WRHA to improve the consent form for autopsies and to improve communication with families about their right, subject to certain legal limits, to refuse consent. Information on this matter should be made available in the Handbook of Patients' Rights recommended elsewhere in this Report.

Recommendations

The Review Committee recommends that Manitoba Health through the RHAs should direct hospitals to notify the OCME of "significant changes" to programs and of program reviews prompted by hospital-related deaths.

The Review Committee supports the OCME efforts to improve tracking of hospital-related deaths, but that further steps in this direction should be integrated with the development of a computer-based information infrastructure for the overall health system.

The Review Committee recommends a review of the role, number and location of MEIs based upon the outcome of the current fee dispute between the Department of Justice and the Manitoba Medical Association representing the MEIs.

The Review Committee recommends no change in the employment status of pathologists.

The Review Committee endorses the recommendation that the OCME develop guidelines for pathologists on the conduct of autopsies to ensure that all relevant perspectives are included.

The Review Committee recommends that the OCME conduct a process analysis of the steps involved with its investigations and autopsies to determine whether a "re-engineered process" could maximize productivity and expedite the autopsy process.

Chapter 8

The Role of the College of Physicians and Surgeons of Manitoba (CPSM)

Introduction

The College of Physicians and Surgeons of Manitoba (CPSM) is responsible under the *Medical Act* for the regulation of the medical profession within the Province. The self-regulation system for the medical profession involves three key functions:

- determining which individuals should enter and remain members of the profession in different specialties;
- monitoring performance and supporting health organizations in the achievement of high clinical standards and ethical behaviour; and
- dealing with complaints raised against its members.

While the CPSM has statutory responsibility for these functions, it is reliant upon other health institutions to perform them, such as the University of Manitoba's Medical School, the Manitoba Medical Association, Manitoba Health, Regional Health Authorities, hospitals, and other health institutions throughout the Province.

There is a special kind of accountability involved with the privilege of professional self-regulation like that delegated by law to the medical profession. Self-regulation is based on the claim that the CPSM has the necessary expertise to ensure competent and safe medical prhigh-riskice. While individual physicians are accountable to their patients, the CPSM is responsible for ensuring that the collectivity of individual physicians perform appropriately. When the profession fails in the task of self-regulation, it is the responsibility of the Minister of Health, the Government of Manitoba and the Legislature of Manitoba to change the terms and conditions under which self-regulation occurs. Self-regulation is built on trust. If a gap develops between those who are regulating themselves and the public they serve, there are likely to be calls for changes to the legal framework and the procedures governing the prhigh-riskice of medicine.

Tragic and preventable events like those documented in the Inquest Report undermine the public's trust in the medical profession. The CPSM recognizes this. It is aware that a number of developments within society have increasingly called into question the assumption that the medical profession has a monopoly on the knowledge required to promote health and deal with illness. There has been the rise of alternative or complementary medicine. New health professions have gained legal recognition and traditional professions, like nursing, have expanded their scope of practice into domains previously occupied exclusively by doctors. Respect for the medical profession has slipped. People still trust their individual doctors, but they are increasingly suspicious of the motives and behaviours of the profession as a whole. A less deferential public is increasingly dubious of the profession's claim that all physicians are solely concerned with the interests of their patients, not with their own financial advantage and reputation. Advances in information and telecommunications technology mean that developments in the health field can be tracked more easily than in the past. A better educated and better informed public is more prepared to debate medical issues with the profession. The preparedness of patients to challenge doctors' decisions is reflected in the steady rise of complaints filed with the CPSM and in the rise of patient advocacy groups pressing their demands within the political process.

As was mentioned, the CPSM has been aware for some time that the process of self-regulation is operating in a more challenging and political environment and has undertaken changes to both its educational and its regulatory approaches. Whether these changes have gone far enough, fast enough is, of course, debatable, but fairness requires a recognition that the CPSM has responded to the decline in public confidence in the profession. There is an educational and a disciplinary dimension to the responses of the CPSM, but both types of responses are meant to ensure the continuing competence and accountability of physicians.

THE ROLE OF THE STANDARDS COMMITTEES

One of the main educational instruments for the medical profession is the Standards Committees that operate at several levels throughout Manitoba's health care system. Authority is granted by law to the CPSM to establish and operate such committees. Their role is to review medical practice in various health care settings to determine whether anything can be learned from a death or potential harm to a patient. The CPSM has established a Medical Standards Committee for the entire province, as well as a Pediatric Death Review Committee to review all deaths of children in the Province. Back in 1994, the CPSM delegated authority to standards committees for each program operating at the HSC. Since regionalization, the operation of the standards committee process has been moved to the regional level under the auspices of the Winnipeg Regional Health Authority.

In the hospital setting, it is typically health professionals and administrators who refer matters to standards committees for investigation. Patient concerns would normally be referred to the complaints procedures operated by the CPSM, as is discussed below. The Office of the Chief Medical examiner (OCME) which conducts autopsies into reportable deaths, also reports deaths to standards committees for investigation. On these last two points, it should be noted for the purpose of the later discussion, that the CPSM has never received a written complaint from any of the parents of the 12 children who died in the pediatric

cardiac surgery program in 1994. Also, the OCME did not refer any issues related to medical practice in the pediatric cardiac program in 1994 to the standards committees, apparently because the autopsies of the 12 infants were delayed in being finalized and in the interim the inquest was launched by the OCME.

The deliberations of standards committees with physicians and others, and any criticisms and remedial actions recommended, are protected under the *Evidence Act* of Manitoba from disclosure and use in civil suits before the courts or in disciplinary proceedings conducted by the CPSM. This protection is consistent with the educational purposes of the standards process and is intended to promote open and frank discussions of actions, competencies and areas for improvement. Where a standards committee has concerns which relate to the safety of the public and these concerns are not addressed by the physician, the matter can be referred to the Central Standards Committee of the College, who in turn can refer it to the Registrar for action through the Complaints/Investigation process.

The Sinclair Report raises the issue of whether the current statutory protection against disclosure of the proceedings of standards committees should be removed. We understand that this was a major issue before the Inquest. At page 496 of his report, Judge Sinclair wrote that:

> "... the need for protection from disclosure of the discussions from those proceedings will need to be balanced against the right and the need for patients and their families to know what occurred. The detail of how that could be accomplished is beyond the scope of this report."

The Sinclair Report makes no recommendations on this point.

Lawyers representing the families urged the Review Committee to remove the current protection against disclosure of standards committees' proceedings. This would require amendments to both the *Medical Act* and the *Evidence Act*. To remove the confidentiality protection would likely affect the approach of physicians and other health professionals to the standards committees and would change the internal dynamics of such bodies. Over the years there have been requests from the medical profession to extend confidentiality protection to the Quality Assurance (QA) committees operating in the hospitals. Such protection exists in at least three provinces. Acceptance of such a change might be seen to tip the balance against plaintiffs in civil cases against physicians. However, spokespersons for the medical profession argue that most of the relevant information found in Standards and QA committees is available in the medical records and in the hands of physicians. The provision of such information can be compelled under court rules.

Finding the right balance between the educational and remedial purposes of the hospital committees and the fairness and liability purposes of the legal process represents a serious challenge. Since the *Evidence Act* is the responsibility of the Minister of Justice, the Review Committee recommends further study of the issue by the Departments of Justice and Health.

As indicated in the recommendations preceding this section, the Sinclair Report was very critical of the practice within the Pediatric Cardiac program in 1994 of having the surgeon whose performance was under review serve on the hospital standards committee. Even if there was not another pediatric cardiac surgeon available to participate in the standards committee, it was a clear conflict of interest to allow a surgeon to review his or her own actions. There was the option of referring the problems in the program to the Central Standards Committee process run by the CPSM. Use of this option might have disclosed at an earlier stage that the problems in the program constituted a threat to patient safety. It has always been the policy of the

CPSM to insist that physicians serving as members of the Central Standards Committee withdraw from discussions when they have played any role in the events under investigation. The same principle should apply in standards committees at all levels.

Recently, there have been moves towards the establishment of multidisciplinary standards committees at the Winnipeg Regional Health Authority. The emergence of standards committees operating on a regional level will reduce the number of potential conflict-of-interest situations and allow for the substitution of a physician who was not involved in the events under review. The Review Committee recommends that the multidisciplinary standards committee become the model throughout the Province.

Another positive development in the standards process is the decision by the Executive Committee of the CPSM to recommend to the Council (the final governing body of the CPSM) an amendment to the by-laws of the College which would allow registered nurses and other health professionals to be appointed as members of the Central Standards Committee. A registered nurse has been nominated and as soon as all the legal requirements are completed, she will begin to attend meetings of the Central Standards Committee. In 1994, only physicians served on standards committees. Allied health professionals, including nurses, have recently been added to all standards committees under the Winnipeg Regional Health Authority. The addition of other health professionals will add new perspectives to the review of incidents and to the development of remedial education action, where necessary. Furthermore, the addition of other professionals to standards committees constitutes an important recognition of greater professional parity and collaboration among the various health professionals. This model should be transferred to the provincial level.

THE COMPLAINTS/INVESTIGATION PROCESS OF THE CPSM

There will be situations where the personal conduct rather than the knowledge and skills of physicians is at issue. At times, a physician's incompetence and an incapacity or unwillingness to make improvements in performance also arise. In these circumstances, educational and other remedial actions will not constitute an appropriate or sufficient response and the matter has to be dealt with through the Complaints/Investigation Processes of the CPSM. Since this process is little known to the public and is subject to some misunderstandings of its aims and operations, we believe that it is useful to describe it in some detail here.

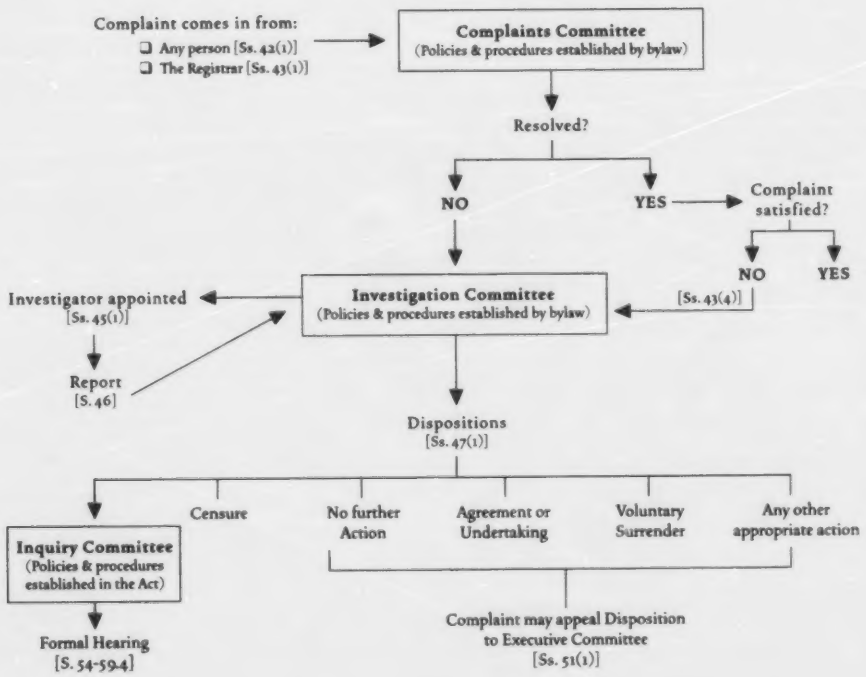
It is important to recognize that the Complaints/Investigation process is developed in accordance with the legal mandate of the CPSM as set forth in the *Medical Act*, as last amended in 1996. The mandate of the CPSM is to establish and maintain standards of medical practice to serve the public interest. It is not the duty of the College to promote the interests of individual physicians or of individual complainants; rather its role is to balance these considerations in the pursuit of the broad public interest. This interpretation means that the College's officers have discretion in the handling of complaints. The Complaints/ Investigation process is not the venue in which private disputes or grievances with physicians are to be pursued – the courts are the forum for such actions. Intimidation at the prospect of confronting the profession and the complexity of the process

will deter some patients from coming forward. The inconvenience and costs of dealing with the complaint process may also be a deterrent for some people. In summary, the complaints process of the College will not capture all the concerns about physician practice that arise. Therefore, it is important that the Standards Committees and the Registrar of the CPSM be attentive to problems and initiate the process without a formal written complaint when issues deemed to affect the public interest arise.

The Complaints Process

The steps involved with the Complaints/Investigation process of the CPSM are outlined in Figure 4. While the vast majority of complaints originate with patients, it is also possible for the Registrar or the Executive Committee of the College of the CPSM (under Sec. 43,1 of the *Medical Act*) to refer issues related to physician conduct to either the Complaints Committee or directly to the Investigation Committee. We were informed by the CPSM that this provision is used often. Where the Registrar receives information (perhaps from the Standards Committee process described above) that involves serious matters requiring immediate action (perhaps related to patient safety) or is not suitable for informal resolution (which is the mandate of the Complaints Committee), he is authorized to refer the matter directly to the Investigation Committee. This provision for direct referral to the Investigation Committee was not available back in 1994 at the time of the infant deaths at HSC. If it had existed, the problems of the pediatric cardiac surgery program **might** have been brought to the attention of the CPSM at an earlier stage.

Figure 4 THE MEDICAL ACT



Complaints about physicians are made to a number of locations – to other health professionals, to authorities within facilities, to elected officials and many directly to the office of the Minister of Health. Of course, patients also complain through the CPSM, but there is a low level of public awareness of the existence and role of the College. Most complaints to the CPSM begin as telephone contacts. Not all complainants are patients. The majority of the matters raised do not require in-depth review. For example, the CPSM is frequently contacted when physicians fail to send in an insurance form, fail to notify of test results, or keep patients waiting unduly. Such concerns can usually be resolved informally and are not counted in the published figures of complaints handled annually by the CPSM. Expeditious resolution of this type of complain is clearly appropriate.

The fact that most public contacts with CPSM do not move beyond these preliminary contacts means that the published statistics on the number of written complaints filed annually with the College underestimate the extent of public concerns. Most Manitobans are unaware of the Complaints Process operated by the CPSM. The CPSM produces a brochure describing the process, but it is not widely distributed within the health system.

A more visible complaints procedure would promote fairness for all patients and strengthen professional accountability. A public survey in the U.K. conducted in 1999 suggested that only 40 per cent of potential public grievances were brought before that country's disciplinary body for physicians. Events in that country led to a new public complaint procedure for the National Health Service (NHS).

Seven criteria were used to design the new procedure:

- awareness/accessibility
- responsiveness
- expeditious
- simplicity
- confidentiality
- impartiality
- accountability
- cost-effectiveness
- contribution to quality enhancement

These design principles are a valuable basis for evaluating the current complaints procedure of the CPSM. On the first criteria of public awareness and accessibility, we believe that the CPSM must do more to inform and educate the public about the availability of procedures to raise concerns about physicians' actions and inactions.

For the College to initiate formal action, a written complaint from a patient or other person is required. A complaint is forwarded to a physician who has 30 days to respond. When appropriate information has been gathered, the matter is presented to the Complaints Committee, whose membership is half physicians and half public representatives. A physician chairs the committee. Four possible decisions can be made by the Complaints Committee:

- dismissal of the complaint;
- provision of a letter of advice to the physician with varying degrees of criticism;
- referral of the issues raised to the Investigation Committee, if the issue is serious enough to warrant further review or if the physician is not receptive to advise on improvement; and
- referral to another appropriate College committee.

A Complaints Committee decision is referred initially to the physician for comment on any possible misunderstanding. Recently the College adopted the procedure of making the physician's response available to the complainant. On the basis of the Complaint Committee's opinion and/or the physician's response, a complainant may request that the matter be referred to the Investigation Committee and this happens automatically. The Complaints Committee's mandate is to promote the informal resolution of less serious concerns and therefore the procedure involves only the circulation of material, but not a formal hearing procedure. In 1999–2000, the College received 455 written complaints. Had formal hearings been held on all these complaints, there would have been a significant time commitment involved for the physicians and public representatives who serve on the Complaints Committee.

The Investigation Committee

If the Complaints Committee believes that a complaint is sufficiently serious to merit more formal consideration, including the possibility of disciplinary action, the case is referred to the Investigation Committee for review. Examples of serious concerns would be allegations of sexual impropriety, breaches of the Medical Code of Conduct, medical mismanagement, etc. The Investigation Committee consists of two physicians and a public representative serving on the College Council. An expert in the relevant field of medicine may be asked to collect information and to provide an opinion. The committee also has the power to apply to the court to compel the production of material which may assist in the investigation. Complainants and physicians do not appear before the Investigation Committee, although they are usually interviewed by the investigator.

Once the investigation has been concluded, the Investigation Committee may decide that:

- no further action is required;
- the physician should be censured, a judgement of wrongdoing which is added to his/her file;
- the matter be referred to the Inquiry Committee of the College for a hearing;
- a written agreement be made with the physician to take corrective action;
- the College accept the voluntary surrender of the physician's licence; and/or
- the College take any other appropriate action including providing the physician with direction advice or specific criticism.

Both the complainant and the physician are informed in writing of the decision of the Investigation Committee and the reasons for it.

Under circumstances specified in the *Medical Act*, a complainant can appeal the decision of the Investigation Committee:

- when no further action is to be taken;
- when there is a letter of agreement with the physician;
- when the College accepts the voluntary surrender of the physician's licence; and/or
- when the College takes other action it considers appropriate.

The complainant does not have a right of appeal when the decision of the Investigation Committee is to censure the physician or to refer the matter to an Inquiry Panel.

THE INQUIRY PANEL

The Inquiry process begins with notification to both the physician and the complainant. An Inquiry Panel of three persons, two physicians and a public representative, is formed. The Panel, the College (prosecution) and the physician (defence) all have legal counsel. The complainant is often called as a witness before the hearings of the Inquiry Panel. Legal counsel employed by the College meets with the complainant in advance of the hearing. Hearings of inquiry panels are generally open to the public. Under the principle that the College exists to protect the public interest, it bears the cost of the prosecution and the burden of proving the case it alleges against the physician. It retains the discretion to handle the case without interference from the complainant since the overall aim of the process is objectivity, fairness and balance, not the settlement of grievances on behalf of patients.

Hearings of Inquiry Panels are generally open to the public. The only grounds for an Inquiry Panel to be held in camera are set forth in Sec. 56(3) of the *Medical Act*:

- public security;
- financial or personal matters where the desirability of confidentiality outweighs the desirability of openness;
- prejudice to a person involved in a criminal or civil proceeding; and/or
- jeopardizing a person's safety.

Between 1995–1996 and 1999–2000, 13 physicians have been brought before Inquiry Panels and in only two cases were their names not made public.

Concern has been expressed that an offending physician may accept a censure at the investigation stage in return for non-disclosure of his/her name. In the past, the CPSM defended such mediated settlements as a way to avoid the cost of inquiry panels. Also, negative publicity and damage to a physician's reputation and practice was seen as too severe a penalty for what might have been an isolated mistake on the part of a physician, in the context of a professional career that was perhaps otherwise exemplary. However, mediated settlements were seen as inappropriate where deficiencies in performance raised concerns about the safety of patients. In response to changing public expectations about physician accountability, the Council of the CPSM agreed in October, 2000 to publish in the CPSMB in-house magazine The Gazette the names of all

physicians who are censured, with the limited exception of situations where there is an identifiable risk to an innocent third party.

Physicians' Responsibility for Disclosing Professional Problems of Colleagues

Physicians are reluctant to challenge and report on deficiencies in performance of colleagues within the profession. The *Medical Act* has a limited reporting requirement. It requires a physician to report only when another physician is believed to be suffering from a mental or physical disorder or illness to such an extent that his/her fitness to practice may be affected and continues to practice when counselled not to do so. In other jurisdictions newer legislation governing health professions has a stronger reporting requirement which includes issues of professional competence.

Notwithstanding the restrictive language of the *Medical Act*, the CPSM takes the position that there is an ethical responsibility to report a colleague when public safety is at risk. The College's Code of Conduct states in Article 26.2 that:

> "When you learn that a deficiency of care has occurred, you should inform the patient and make the responsible physician aware. If the physician is unresponsive or shows evidence of continuing deficiency, the responsible authority must be informed."

This Code of Conduct was not in place back in 1994 when the deaths in the pediatric cardiac surgery program took place. Of course, the Code is voluntary, it relies for its effectiveness on an internalized, subjective sense of responsibility on the part of individual physicians, and it remains very difficult professionally for a physician to accuse a colleague of incompetence. It is worth noting that the Code of Ethics for nurses imposes a much stronger duty to report competencies issues that does the College code. We discuss this contrast in the final chapter of this Report

A Possible Role for "Physician Profiles?"

The concern that physicians protect one another is reflected in the demand from patients' rights and other advocacy groups for the disclosure of the professional records of individual physicians. At present, the CPSM does not disclose the number or type of complaints and/or investigations respecting individual physicians. Section 63 of the *Medical Act* requires confidentiality respecting complaints and investigations, except in limited circumstances. Inquiries to the CPSM about the professional record of a doctor will, however, produce information on:

- conditions imposed on license;
- suspension, surrender or cancellation of registration or a license; and
- the result of every disciplinary proceeding before an Inquiry Panel which resulted in a conviction.

The CPSM Newsletter and the Annual Report for the College provide periodic summaries of disciplinary action. Table 2 provides a summary of the different types of disciplinary action during the past five years.

Such a table provides one overview of the collective performance of the profession, but does not answer questions about the performance records of individual physicians.

Table 2

DISCIPLINARY ACTION STATISTICS

	Number Complaints Received	Number referred to IC	Number appealed to IC	Number Closed by IC	Number Censures	Number Inquiries	Number Publications re: Suspension/Loss of License
1999-2000	455	48	29	71	3 (3 w name)	2	1 (1 w name)
1998-1999	260	35	24	72	8 (3 w name)	2	3 (2 w name)
1997-1998	292	61	33	98	9 (5 w name)	5	4 (3 w name)
1996-1997	276	38	32	94	4 (2 w name)	4	2 (2 w name)
1995-1996	382	40	*	59	7 (5 w name)	3	3 (3 w name)
1994-1995					3 (1 w name)		
1993-1994					2 (1 w name)		
1992-1993					1 (1 w name)		
1991-1992					2 (2 w name)		
TOTAL	1,465				39 (23 w name [59%])		13 (11 w name)

* - unknown

THE CONCEPT OF PHYSICIAN PROFILES

The Committee met with representatives of the Coalition for Access to Physician Practice Information to discuss a submission they made to the Minister of Health and his department in February, 2001. The Coalition is advocating the publication of "Physician Profiles," which would be readily available to members of the public. The profiles would present concise information about physicians in five areas:

Education and training – The CPSM already gathers this type of information and would be agreeable to a legislative amendment requiring periodic updates and requiring that the information be more accessible to the general public.

Employment History – The CPSM would agree to the collection and publication of this information, with the proviso that the onus would be on the physician to report accurately and without the expectation that the College had verified the information.

Malpractice actions – The CPSM does not currently gather information on civil actions taken against physicians. Such information is available through the court system. There would be a cost involved in gathering and publishing this information. Many suits are settled out of court or abandoned as not capable of being proven. If this were a requirement, the onus could be put on the physician to disclose, provided there was not an assumption that the College had verified the information.

Criminal convictions – The CPSM maintains records of certain criminal offences in Manitoba and seeks information as to the criminal history of a physician entering Manitoba. The College endorses

a legislative amendment that would compel physicians to disclose such information on an annual basis. Much of this information is available currently through the criminal courts and there would be a cost involved in compiling it for public distribution.

Discipline or censure – The *Medical Act* provides that conditions of practice, license suspension, surrender or cancellation is included in the physician Register, which is accessible through the College. The CPSM endorses a legislative amendment that compels physicians to disclose such information on application and on an annual basis. The CPSM is prepared to review disclosure of this information to the public, provided there is some mechanism for the protection of innocent third parties.

The above discussion indicates that the Coalition for Improved Access to Physician Information and the CPSM are in substantial agreement over the kinds of information about physicians which should be available to the public. Providing Manitobans with more and better information about the quality of medical practice in general and about the performance of individual physicians is an aim which this Committee endorses. This must be done, however, with appropriate regard for the rights and reputations of doctors, for the protection of the rights of third parties, and for the cost-effectiveness of different ways of generating and distributing information.

The Review Committee supports the principle of increased public access to information concerning the qualifications, competencies and track record of the physicians and surgeons who treat Manitobans. However, implementing the principle is not as straightforward as might appear at first glance. There is some disagreement over how the principle of public access to physician information should be implemented in practice. As a legally-constituted regulatory body, the CPSM is more concerned with the legal requirements for implementing the principle than is the Coalition, which is advocating on behalf of the principle of the public's right to know more about the records of their doctors.

It needs to be recognized that amendments to the *Medical Act* to make information about physicians and their records more readily available would have to be consistent with the provisions of the *Freedom of Information and Protection of Personal Privacy Act* (FIPPA) which was enacted in 1998. FIPPA controls the manner in which public bodies collect personal information from individuals and to protect individuals from unauthorized use or disclosure of information by public bodies. The *Act* also establishes a Privacy Assessment Review Committee to review uses of personal information such as linking or matching of information databases. The coverage of the *Act* covers all public sector bodies, including health authorities and hospitals.

There also exists the *Personal Health Information Act* (PHIA) which was enacted in 1997. The PHIA has both access and privacy provisions. It covers both public health institutions and private personal care homes. It seeks to promote a consistent approach to the handling of personal health information because many persons other than health professionals now obtain, use and disclose such information in different contexts and for different purposes. The *Act* requires that all health care personnel receive education about its provisions and sign a pledge of confidentiality. In addition to privacy protection, the PHIA also promotes greater access to personal health information. Individuals have the right to access their own health records. Not only will this remove the secrecy surrounding medical records, it will require that health personnel be more careful in recording information since patients will have the right to view records. Given the intimate and

sensitive nature of personal health information it is vitally important that a consistent statutory approach be followed. In reconciling the statutory aims and provisions of FIPPA, PHIA and the *Medical Act*, attention must be paid not only to the rights of consumers but also to those of professionals.

Beyond ensuring there is statutory consistency, implementation of the principle of public access to physicians' histories raises practical issues of communication of the relevant information. The Coalition and the CPSM appear to disagree on how accessible information about physicians should be. The Coalition seems to envisage brochures available through doctors' offices and hospitals describing the practice profiles of physicians. Such information would also be available on-line, including through public libraries. In the United States, the Federation of State Medical Boards received in April, 2000, a report from a committee on the issue of physician profiling. The committee recommended that physician profiles should be available to the public in a user-friendly format. Information should be received from primary sources, verified by the physician, and unverified information should be clearly designated. Physician profiles should be provided free to the public or at cost and a Consumer Guide should be developed to help members of the public understand and weigh the information in the profiles. Massachusetts is generally seen as the leading state in terms of the operation of a physician profile program, which is overseen by the State Board of Medical Examiners. There are similar programs operating in 15 other states and the number is growing.

The Coalition brief assumes that the public will use physician profiles to make better informed choices about physicians and medical procedures. Not only will this promote greater physician accountability, it will over time cause improvements in the health care system as less competent and/or conscientious physicians are pressured to improve their knowledge and skills. The available evidence on this point is mixed and not definitive, but it suggests that most members of the public do not use physician profiles to the extent that proponents suggest they do. A 1996 survey by a federal agency in the United States (Agency for Health Care Policy and Research) found that most people relied on personal recommendations from family, friends and doctors in selecting physicians or surgeons. Eighty per cent of the respondents said physician profiles with comparative data on performance would be useful, but only one-third had ever used the information to make medical choices. In situations where an individual needs to see a specialist, there may, in fact, be no choice involved. Of course, reliance upon the experience and opinions of others is a familiar practice for choosing a doctor and in those instances such references may be based on consultation of physician profiles.

There is the concern that focusing on negative information about physician performance, such as the number of malpractice suits, could potentially be unfair to physicians, especially those who undertake high risk procedures. A focus on the records of an individual physician may also ignore the problems of attributing outcomes to individuals in a team setting and may cause divisions between doctors and nurses and other allied professionals when unwanted outcomes occur.

Proponents of physician profiles insist that if information is presented in context, with appropriate explanatory material, consumers will be able to interpret results and decide which physician is best for them. Fairness to physicians might also require that positive accomplishments be recognized in profiles – awards, additional education, medical breakthroughs, etc. There is also the issue of whether negative information should be erased from a physician's profile after a certain period of time or after the completion of additional education and perhaps a clinical audit of his/her practice.

Information is not a free resource. It is true that some of the information to be presented in the proposed physician profiles is now collected by the CPSM but there is the issue of who should pay for the collection, verification, compilation, publication and distribution of the wider range of information now being sought. Internet distribution of the information is an option. Access to computers and use of the Internet is still greatest for higher socio-economic groups. A model for more universal public access could be found in the example of a consortium in New York City which created a user-friendly web site offering access to health information through terminals in libraries. The cost of creating and maintaining the site was significant, even with four partners (City, University of New York Office Library Services, METRO, the New York Academy of Medicine and the New York Public Library) and a federal grant to get started.

Providing background and disciplinary information on physicians is different from the publication of outcomes data for different types of surgeries discussed earlier in the section on informed consent. Some of the problems involved with producing valid comparative, consistent, fair, comprehensible and timely data on surgical outcomes were discussed there. Here, we would only make the point that the simultaneous publication of outcomes information and profiles focussed on problems would impact disproportionately a select group of surgeons who undertake low volume, high-risk procedures.

The Importance of Continuing Medical Education

Improved disciplinary procedures and the publication of physician profiles represent two approaches to promoting high standards of medical practice. However, good education and training relevant to the needs of modern health care, careful appraisal of doctors upon appointment, support for continuing learning and development and periodic recertification of all doctors' competence to practice, are the real foundations for preventing poor individual performance. Procedures for ensuring that doctors remain up to date with medical developments and maintain their clinical skills are assuming increased importance in all health care systems. The procedures go by different names – recertification, continuing medical education, revalidation and maintenance of professional standards, are labels used in different countries.

In 1999, the General Medical Council of the United Kingdom adopted the principle that all physicians would have to show regularly throughout their careers that they remain fit to practice. This move towards stricter self-regulation was adopted by the Council in the aftermath of several disturbing breakdowns in sound medical practice, including deaths in the pediatric cardiac surgery program in Bristol, England. The revalidation process means that doctors will be monitored to ensure competency and to ensure that medical knowledge is current. Those who fail to achieve the required standards will be struck off the medical register. A working revalidation model – including how the peer-review process would work and how the process would be financed – were to be worked out through a consultation process lasting two years. Significantly the British Medical Association feared that the revalidation proposal would require excessive bureaucracy, would be costly and would have to be funded by government.

In Canada the two primary bodies for post graduate medical training are the College of Family Physicians and Surgeons (CFPC) and the Royal College of Physicians and Surgeons (RCPS) for all the medical specialties.

The CFPC has for several years operated a maintenance of competence review process (MAINPRO) which requires attendance at a certain number of continuing education sessions on a yearly basis over three years. Failure to complete the requirement leads to the revocation of status as a member of the College, although the physician is still allowed to practice. The RCPS began a Maintenance of Certificate Program in January, 2001. It requires 250 hours of continuing medical education activity. A number of categories of activity are allowed, but a significant number of hours must be formal education in the physician's area of specialty. Again, failure to obtain the required credits leads to a loss of fellowship status, but the physician is still permitted to practice.

In Manitoba, the CPSM notes a physician's voluntary completion of 25 hours of continuing medical education for the previous two years. If a physician undergoes a clinical audit, the information on continuing education is verified, but otherwise the system works on the honour system. The CPSM is in discussion with Manitoba Health concerning a continuing education requirement for those physicians who do not have certification from either of the specialty colleges. The College has also participated in meetings held over the past several years of the Federation of Medical Licensing authorities of Canada (FMLAC) which is developing a national program for the assessment and remediation/enhancement of physician performance.

In 1999, the Alberta College of Physicians and Surgeons launched an initiative called the Physician Achievement Review (PAR). PAR is designed to provide doctors with information about their medical practice through the eyes of those they work with and serve. Every five years each physician in Alberta will have his/her performance reviewed by way of questionnaires completed by 25 patients, 8 physician colleagues and 8 non-physician healthcare co-workers. An independent firm compiles the confidential replies and provides the doctor with detailed aggregate responses, as well as a comparison to the summary profile of all physicians with similar practices. Five attributes of the physician's performance are reviewed:

- clinical knowledge and skills;
- communication skills;
- psychosocial management;
- office management; and
- collegiality.

PAR information is used strictly for educational purposes and only in extreme circumstances, such as the risk of immediate harm to the public, would a physician be referred for possible investigation. An inventory of learning opportunities is available and Alberta's two universities are partners in developing supports for physicians needing help. PAR is administered by the Alberta College of Physician and Surgeons and paid for by physicians at an estimated cost of $40 per year per physician. By incorporating the perspectives of allied health professionals and patients into the performance review, the PAR program represents an important initiative by the Alberta College of Physicians and Surgeons. It may become the model for similar programs in all provinces.

In the case of the unacceptable medical practice, prevention is clearly preferable to a cure. More effective means must be found for identifying, supporting and, if necessary, disciplining doctors whose performance is below the standards patients should expect. Achieving high-quality medical care requires much more than tackling the small minority of doctors whose professional knowledge and skills and/or behaviour is

poor or inappropriate. Superior medical care involves initial and ongoing education; the use of rigorous quality assurance procedures; remedial and enhancement techniques for doctors experiencing difficulties of a professional or a personal nature; and open procedures for disciplining doctors who breach professional standards and codes of conduct.

Recommendations

The Review Committee commends the CPSM for recent reforms to its Complaint/Investigation procedures which will contribute to making the disciplinary process more accessible, responsive, and impartial. In particular, the change made in 1996 to the *Medical Act* which allows the Registrar or the Executive Committee of the CPSM to refer issues to a Complaints Committee without a formal written complaint having been filed represents a significant improvement over what existed at the outset of the Inquest. The Review Committee was gratified to learn that this provision has been used frequently and that, if the Registrar is made aware of a serious situation requiring immediate action, the matter is referred to the Investigation Committee rather than the Complaints Committee, where the emphasis is more on the informal mediation of complaints, not on formal discipline. It is anticipated that should similar problems to those that existed in the HSC's pediatric cardiac surgery program in 1994 arise in the future they would come to the attention of the CPSM earlier and hopefully would be addressed in an effective manner.

Other changes to the Complaints/Investigation procedure have strengthened the application of the principles of natural justice or fairness. The automatic provision to a complainant of the physician's response to an initial complaint will allow patients to make a more informed case when a matter proceeds to an investigation. Another improvement is the College's decision in October, 2000 to publish the names of all physicians who have been censured, except where there is a risk of harm to third parties. Finally, the College has expressed openness and a willingness to discuss ways to improve patient access to the performance records of physicians.

The Review Committee believes that the real problem with the Complaint/Investigation procedure of the CPSM is that it is unknown to the vast majority of Manitobans. The availability of a pamphlet and a web site does not guarantee sufficiently that health consumers will be aware of the role of the College in promoting quality medical practice and in dealing with complaints about the conduct of physicians.

The Review Committee recommends that the CPSM adopt a more pro-active education strategy to promote public awareness of the role that the College plays within Manitoba's health care system, including its role in dealing with complaints about physician behaviour and its disciplinary powers.

Such a strategy would include more widespread distribution and more prominent display of brochures describing the College's role and the rights of patients under its Complaints/Investigation procedure. It would involve College Officers appearing in educational forums, before community groups, at conferences, on the media and in other venues to describe and explain the role of the College.

The Review Committee recommends that the CPSM Code of Conduct be modified to include a duty on the part of physicians to inform patients and others about the role of the College and the availability of the complaint process.

The CPSM Code of Conduct has sections dealing with the responsibilities of physicians to the profession, to the College and to society, but there is not a duty to promote public awareness of the College and its procedures for handling complaints. The other responsibilities imply a duty to inform patients about the College and this should be recognized in the Code.

The Review Committee recommends that the CPSM work with Manitoba Health and other interested groups to develop a system of "physician profiles" describing the education, experience, training, awards, disciplinary history and other information deemed relevant for each physician practicising in Manitoba. In the context and format for physician profiles, a balance must be found between the public's right to know and easy access to information with the right of physicians to a measure of privacy and to an accurate, balanced and fair interpretation of their history of medical practice.

Several questions could be raised about the recommendations that the CPSM play a larger role of public education. The profession might see this as more appropriately the responsibility of Manitoba Health and perhaps of the Regional Health Authorities. However, the CPSM is not the Manitoba Medical Association, the professional organization which represents doctors. The CPSM has been endowed with public authority to allow physicians the privilege of self-regulation and with this authority comes an obligation to promote public awareness of its role. This educational role will be shared with other bodies in the health system and there should be discussions with Manitoba Health and others about coordinating and perhaps cost sharing in the field of public education.

The Review Committee recommends that the CPSM proceed to develop a more formal program of Continuing Medical Education for its members.

The Review Committee recommends that the CPSM adopt the Physician Achievement Review process used in Alberta to incorporate both peer review and patient input into the evaluation of physician performance.

The Review Committee recommends that the CPSM, in consultation with Manitoba Health, develop over the next five years a program for the periodic recertification of doctors as a means of ensuring quality practice and maintaining public confidence and trust in the profession.

The medical profession today definitely faces a more challenging environment than in the past. There are pressures for more direct patient and public involvement and for more accountability for physicians, both individually and collectively. The process of professional self-regulation has been reformed, but more needs to be done to ensure timely responses to identified problems in clinical practice. In addition to ensuring physicians are qualified to practice at the beginning of their careers, the CPSM must strengthen its commitment and support for the concept of lifelong learning. Identifying and tackling serious or persistent clinical problems in a timely manner should be emphasized over dealing with problems after they enter the complaints process.

Chapter 9

The Future of Pediatric Cardiac Surgery and The Western Canadian Children's Heart Network

Introduction

The checkered history of the pediatric cardiac surgery at the HSC since the 1950s and the tragic events of 1994 convinced the Review Committee that renewal of a program for Manitoba alone would involve variable outcomes and higher than acceptable risks for patients.

Research literature indicates that larger pediatric cardiac surgery programs around the world tend to deliver better results than smaller programs. The evidence suggests that pediatric cardiac teams that perform fewer than 100 open-heart cases per year have more difficulty in maintaining the surgical and other competencies necessary to ensure high-quality care and a ratio of positive outcomes, which compares favourably to standards within the field. The HSC program was usually slightly below or just at this threshold of 100 cases annually. Research suggests that the optimal number of cases per year to ensure continued competencies and the best ratio of positive outcomes is in the 150–200 cases per year range. Never in the history of the pediatric cardiac surgery program was the optimal number of surgeries performed at HSC on an annual basis.

The Review Committee is mindful of the fact that caution must be exercised in interpreting the numbers presented above. The "success rate" of a surgical program can be measured in various ways, but the tendency in public commentaries is to focus on the number of deaths. Also, success rates for surgical programs must be adjusted to take account of a number of factors, such as the severity of the illnesses involved and the mix of different types of procedures undertaken. In summary, to suggest that there is a precise minimum and a precise optimal number of cases which will guarantee positive outcomes in pediatric cardiac surgery would be misleading. There will always be risks and untoward events in pediatric cardiac surgery programs.

Nevertheless, the problems and the fluctuations in the quality of care documented in the Sinclair Report provide compelling evidence that the patients and families were exposed to an unacceptable level of risk in the pediatric cardiac surgery at HSC during 1994. Rather than restart the program, the Review Committee

recommends that the Province of Manitoba participate in the proposed Western Canadian Children's Heart Network (WCCHN).

PEDIATRIC CARDIAC SURGERY IN WESTERN CANADA

The proposal for the WCCHN emerged out of discussions among Deputy Ministers of Health from the four western provinces that took place in 1997. An Ad Hoc Committee to address collaboration among the provinces in health care was established and the first area selected for examination was pediatric cardiac surgery.

There are five pediatric cardiology programs in Western Canada, located in Vancouver, Edmonton, Calgary, Saskatoon and Winnipeg. Pediatric cardiac surgery is currently performed in Vancouver and Edmonton. Between the suspension of pediatric cardiac surgery at HSC in February 1995 and August 2000, approximately 550 patients were referred out-of-province, at a total cost of approximately $7 million. Patients were sent to a number of locations, not all in Western Canada, but the greatest number of referrals were to Saskatoon's Royal University Hospital and to Toronto's Hospital for Sick Children. In the past, there has been competition between facilities and provinces for the approximately 600 cases of pediatric cardiac surgery that arise annually for all of Western Canada. Interprovincial cooperation and partnership must occur to provide optimal care and maximize the benefits of specialized expertise and professional collaboration.

THE WESTERN CANADIAN CHILDREN'S HEART NETWORK

A number of meetings and reports led to the production of The Final Report of the Western Canadian Children's Heart Network Implementation Committee (March 2000). The WCCHN involves a formal affiliation of the five centres with expertise in pediatric cardiology. The network will have the following functions:

- to assess results of clinical care (surgery and interventional cardiac catheterizations) at all centres on an ongoing concurrent basis in order to identify potential problems as they arise;
- to compare the results of clinical care to North American standards;
- to collaborate between centres on complex clinical cases;
- to share educational activities including morbidity and mortality rounds;
- to share patient/family related support resources;
- to collaborate on future research and educational endeavours;
- to share and discuss plans that will have impact on children's cardiac care from all member institutions, providing feedback as necessary.

In order to fulfill these functions, a coordinator will be selected to arrange meetings, to review and circulate data, to manage collaborative projects and to maintain telecommunications links.

The Role of Telemedicine in the WCCHN

Telecommunications will play a key role in the operation of the Network. The WCCHN will involve the use of high-speed telemedicine links for real-time interactive assessment of clinical cases by specialists from multiple sites advising, supporting and sometimes mentoring one another regarding appropriate treatments. Information and telecommunications technology to support this level of sophisticated interaction in the health field is not presently available. With the Province of Manitoba playing the lead role, a request for consulting services to provide an inventory of current technology and the necessary upgrades to make the network concept viable was issued in October 2000. The contract was issued to KPMG and a work plan is to be ready by the end of June 2001.

Outcomes Data from the WCCHN

The WCCHN is a complex project and numerous issues could be raised for discussion. We will restrict ourselves to features which seem most germane to the mandate of the Review Committee. We will begin with the matter of quality medical care. The Review Committee is convinced that the Network will facilitate the provision of high-quality care to children with heart disease in Western Canada. It will do this by creating the necessary volume of cases and the opportunities for the participating surgeons to refine their skills in an extremely challenging specialty. It will provide an expanded pool of knowledge, peer review of performance and advice on outcomes through monthly video-conferencing arrangements. Data from the program will be collected and stored electronically, shared with other member institutions and be submitted to the Pediatric Cardiac Care Consortium for comparison to the outcomes in similar programs in North America. The Network will allow for specialists to be licensed in more than one province and it will support travel for specialists to other cities for purposes of training and filling-in for vacationing specialists.

The Health Sciences Centre and the WCCHN

Membership in the WCCHN will be based on the referral nature of the program and not on the presence of a pediatric surgery program at the member institutions. What this means for Manitoba is that the Pediatric Cardiology program at HSC in Winnipeg, which has not operated a pediatric cardiac surgery program since 1995, will be part of the Network. Pediatric cardiologists in Winnipeg will be able to refer patients to the two centres where surgeries are performed. The pediatric cardiologist selected to represent HSC will serve on the Network Steering Committee and will participate in discussions with professional colleagues on topics such as diagnosis, treatment, data development, quality care initiatives and evaluations.

For the foreseeable future, it is not recommended that there be a resumption of pediatric cardiac surgery at HSC. Longer term consideration should be given to conducting high volume, low risk surgical procedures at HSC. The Review Committee recognizes that there are hardships for families involved, with travel to referral centres out-of-province. But we believe that the Network represents the best option to ensure safe,

high-quality care in the challenging field of pediatric cardiac surgery. In some respects, participation in a four-province regional network follows the same logic that led to regionalization in a Manitoba context, namely that it provides the scale of operation necessary to enable high-quality, full service programs.

ITINERANT SURGEONS AND THE WCCHN

There is one aspect of the medical component of the network proposal that requires clarification – that is, the movement of surgeons to other surgical and non-surgical centres in the network to conduct operations. This arrangement would seem to contradict the importance usually assigned to continuity and teamwork in the surgical process. It may be the intention to have itinerant surgeons conduct only high volume, low risk procedures outside of their "home" institutions and away from their own surgical teams, however the impact on the patient must be recognized. Care of a patient undergoing surgery begins prior to and extends past the completion of the surgical procedure. Ideally, post operative care should be managed by the attending surgeon to allow for a continuity of care and consistent management of said patient. Within an itinerant surgery model, fragmentation may occur given the limited time frame that surgeon is present at the host facility. This creates the potential of risky situations and will need to be addressed.

There is also the issue of licensing physicians to practice in other jurisdictions. Some provinces, like British Columbia, require that physicians regardless of the circumstances, be fully licensed to practice within their borders. There are provisions in the Medical Acts of other provinces, such as Manitoba, for limited practice by physicians, usually in medical-education settings or to fulfill health needs in medically underserviced areas. These jurisdictional issues can probably be resolved. If successful, the WCCHN could become a model of both constructive collaboration among governments to improve health services and contribute to a reduction in the current restrictive barriers to physician practice among the provinces.

SUPPORT FOR PATIENTS AND FAMILIES USING THE WCCHN

The advantages of the Network in terms of improved medical care are clear to the Review Committee. Less clear is whether the designers of the WCCHN have at this point given sufficient attention to ensure that the experience of patients and their families within the network will be trouble free and positive. The Final Report on the WCCHN mentions that video-conferencing will be used to allow patients and families "to meet" clinicians at the referral centre prior to transfer to provide background information and to relieve anxieties during a stressful period.

The WCCHN proposal also refers to the development of a common pamphlet/or consent form to be provided to patients and families. Patient satisfaction is designated as one component of the formal, in depth evaluations to be conducted every three years beginning after two years. Patient surveys would be used to complete this component of the evaluation.

Based upon the experience of the families involved with the HSC program and a small sample of families who travelled out of province to other centres, the Review Committee is concerned that to this point in

the development of the WCCHN, not enough attention has been paid to meeting the needs of families. For example, in our Chapter Five on Informed Consent we discussed the importance of patient-physician communication in terms of ensuring that consent was voluntary, involved full disclosure and resulted in the fullest possible understanding of all aspects of the surgery. In the technological context of a videoconference process generating trust and confidence between the patient and the physician will probably be even more intimidating and difficult than in a face-to-face meeting. The WCCHN proposal describes a combined handbook and consent form which seems designed to fulfill the strict legal requirements for informed consent, but does not address adequately the crucial and sensitive issues of communications between patients, families, physicians, nurses and other health providers within the consent process. This is an example of how telemedicine takes us into new, largely uncharted territory in terms of the need to develop new approaches to issues like informed consent.

A second area of concern involves the need to provide the fullest possible range of supports to the families facing the stressful situation of leaving the province for delicate and risky surgery on their children. A handbook alone will not be sufficient assistance to families. There has been a financial support program (covering airfare, accommodations, ground transportation and per diem allowances) operating out of HSC since the suspension of the pediatric cardiac surgery program in 1995. There is also an experienced neonatal transport team at HSC Children's Hospital. The Review Committee believes that when out-of-province travel for pediatric cardiac surgery becomes an institutionalized part of Manitoba's health care system, there should be a coordinating office established. This office would report to the physician selected to serve on the WCCHN Steering Committee. The office should be directed by a nurse from the pediatric field. The office should provide "one-stop" service to the families – including travel arrangements, coordination with the personnel at the receiving facility, the transfer of medical records, dealing with inter-jurisdictional issues, arranging follow-up care for families upon their return and, most importantly, dealing with the questions and concerns that families will inevitably face. In summary, the Review Committee sees it as essential that there be a well coordinated and integrated approach to service provision within the network and that there be a visible "human face" who embodies the qualities of professional, competent and empathetic care.

Recommendations

The Review Committee recommends that for the immediate future, there should be no restart of the pediatric cardiac surgery at HSC. Pediatric cardiac surgery programs are costly to support in terms of programming funding. Fiscal resources that would be utilized for a Manitoba pediatric surgery program should be redirected to support the WCCHN.

The Review Committee recommends that the Province of Manitoba continue to support and play a lead role in the development of the WCCHN as basis for providing high-quality pediatric cardiac surgery to Manitobans.

The Review Committee recommends that in the development of the WCCHN that attention be paid to the needs of families in terms of the concerns raised above. Patient experience and

patient satisfaction should be a larger component of the formal in-depth evaluation scheduled to take place several years after the launch of the program.

The Review Committee recommends that the WCCHN be seen as a possible model for extension of collaboration with pediatric surgical programs in Eastern Canada and for other specialty programs where Manitoba could benefit from participating in interprovincial programs.

Chapter 10

The Role of the Minister of Health and Manitoba Health

Introduction

It is a fact of political life that nearly all developments within Manitoba's complex and dispersed health care system can potentially be brought back to the doorstep of the office of the Minister of Health. Arguably, the job of Health Minister is the most challenging and politically sensitive of all the positions within the provincial cabinet, with the possible exception of the position of Premier.

Given our system of cabinet-parliamentary government, authority over policy and spending is concentrated in the hands of the Premier, the Cabinet and individual ministers. Yet the refinement and implementation of broad provincial policies and the actual expenditure of funds is done to a large extent by semi-independent bodies like municipalities, schools, colleges and universities, health care institutions and Crown corporations. Despite this diffusion of responsibility, the political process operating through the adversarial and partisan forum of the Manitoba Legislature, obliges individual ministers to be answerable for all that transpires within their portfolios of departmental and non-departmental organizations.

In Chapter Two, where we provided an overview of the different types of accountability operating within Manitoba health care system, we cautioned against an insistence on too strict an interpretation of the principles of individual ministerial responsibility.

It is appropriate that the Minister of Health be obliged to explain, and at times defend, actions within the health care system that lead to unpopular and/or unfortunate outcomes. In this role the Minister serves as a focal point for the achievement of ultimate accountability to the public. Answerability, however, should not be confused with the automatic obligation to resign their portfolio. Health Ministers should not be expected to resign their cabinet positions every time something goes wrong in the health system, especially if they were not involved in the matter and did not approve of what was done. It is unrealistic to make the minister absolutely accountable for everything. There are enormous demands on the time and energies of the minister. Only a small per centage of the thousands of decisions made daily within the health field are

ever brought to his/her attention. Health spending represents nearly 40 per cent of the provincial budget and over 60 per cent of that spending is done through somewhat arms-length institutions and individuals who do not fall directly under the management control of the Minister and the Department of Health.

ACCOUNTABILITY AND THE REGIONAL HEALTH AUTHORITIES

The process of regionalization was begun in 1997 with the passage of the *Regional Health Authorities Act*. The *Act* has been amended several times since 1997. In general terms, the *Act* and its regulations give RHAs responsibility and authority to plan and coordinate the delivery of all health services within the 12 regions where they operate. There are also other statutes, such as the *Hospitals Act* and the *Mental Health Act*, that prescribe more specific responsibilities for institutions operating within the RHA framework.

Regionalization has significant implications for the role of the Minister and of the Department of Health. This is not the place to review the progress to date in terms of putting the regional structure in place and developing the shared understandings and norms of behavior necessary to make it work as intended. The concern here is with the role of the Minister and the Department of Health in terms of the clear assignment of responsibility and accountability.

To uphold the principle of ministerial responsibility, the *Regional Health Authorities Act* assigns important authority to the Minister of Health in relation to the Regional Health Authorities (RHAs). "The Minister has responsibility and authority to establish the expectations related to the Minister's delegation of responsibility and authority to the RHAs and to ensure that those expectations are effectively communicated to all RHAs." (Manitoba Health, Achieving Accountability, 1999). The *Act* provides the Minister with a number of prerogatives to fulfill his/her responsibilities:

- authority to issue directives to RHAs
- authority to withhold funding
- authority to appoint and remove directors from boards of RHAs
- authority to approve board bylaws
- authority to enter into agreements with RHAs
- authority to require additional information from RHAs
- authority to place a facility under outside management.

These powers give the Minister of Health clear authority to intervene in the operation of the RHAs. However, in the spirit of devolved decision-making and community responsiveness that is at the heart of the regional health care delivery model, such interventions should be the exception and occur infrequently. A persistent pattern of adverse outcomes in a surgical or other medical program would be a situation where a Minister of Health might feel obliged to intervene.

For the Minister to provide policy leadership and scrutiny of the operation of the health care system, he/she requires timely information on the actions and performance of the RHAs. The *Regional Health Authorities Act* imposes several reporting responsibilities on the RHAs:

- required to report in the time and form specified by the minister on a health plan for the region;
- required to provide any reports and statistical information that the minister may require;
- required to submit within six months after the fiscal year an annual report; and
- a requirement that the Council of Board Chairs for RHAs report regularly to the Minister.

In addition to the information which flows from the RHAs, the Minister and the Department use the research services of the Manitoba Centre for Health Policy and Evaluation (MCHPE). The MCHPE is an internationally recognized group of researchers from different disciplines. The Department of Health negotiates annually with MCHPE to produce five or six studies that can provide an independent evaluation of population health as it relates to programs and services provided by RHAs and hospitals.

The Transformation of Manitoba Health

The regional model assumes that Manitoba Health will provide policy frameworks, set health care standards and monitor the performance of health institutions. The Mission Statement for Manitoba Health states that the department is:

> "To provide leadership and support to protect, preserve and promote the health of all Manitobans. This mission is accomplished through a structure of comprehensive envelopes encompassing program, policy and fiscal accountability; by the development of health public policy; and by the provision of appropriate, effective and efficient health and health care services" (Manitoba Health, Annual Report, 1999–2000).

In a companion vision statement, the Department talks about leading the way to quality care, empowering Manitobans with knowledge and choices, building partnerships for healthy communities and fostering innovation. These are sweeping and ambitious objectives. However, the Review Committee has serious doubts about whether Manitoba Health with its present organizational design and analytical capacity is capable of fulfilling its mission and vision.

As the regionalization process proceeds, Manitoba Health will be placed more and more in the position of having to "steer" the complex and dispersed health care system by "remote control." Manitoba Health is already less involved with the direct delivery of health programs than in the past. It cannot rely as much on "command and control" as it once did. Today, and increasingly into the future, Manitoba Health personnel will have to provide policy and managerial leadership across organizational boundaries rather than within the framework of an integrated department. New structures, new kinds of knowledge and new skills will be required within Manitoba Health for it to serve the Minister effectively, to set the parameters of health care delivery, and to hold the health institutions operating with delegated authority accountable for their performance.

We describe the "core" future roles of Manitoba Health as follows:

- to provide policy planning and advice to the Minister and the government;
- to provide province-wide medium to long-range planning;
- to ensure that budgetary allocations reflect long-term plans and current government priorities;
- to prescribe health care services that must be provided and to ensure compliance with health care standards;
- to monitor performance and to conduct periodic, in-depth evaluations of selected programs;
- to develop information reporting and information management approaches to ensure program and financial accountability.

At present, Manitoba Health has too little capacity to perform these roles. The senior leadership of the Department recognizes this and they have put forward proposals within government to restructure the Department and to expand its capacity in crucial areas. If changes are not made within Manitoba Health there is a significant risk that the health care system will be reactive rather than anticipatory, further problems will develop, weaknesses in programs and delivery systems will not be detected, and program and financial accountability will be weak.

The above discussion should not be read as a criticism of the current personnel in Manitoba Health. The problems involve system shortcomings, far more than individual shortcomings. Redefining and changing the operations of Manitoba Health represents a major challenge. There will be financial costs involved in creating the organizational and analytical capacity to enable the Department to fulfill its changed role. Current employees will have to be supported through education and training to acquire the knowledge and skills required to work with a variety of outside organizations.

The Minister of Health and the Executive Management Committee recognize the need to transform the Department. Since 1997–1998 there has been a reduction in staff from approximately 2,500 down to approximately 1,100 in 1999–2000. In part, this reduction reflects the withdrawal of the Department from the direct management of service delivery. More of the transactional work of dealing directly with health institutions now takes place at the RHA level. There has been a significant migration of department staff to work at the RHAs, especially at the WRHA. This has been due to a number of factors: an opportunity to "make more of a difference," a more dynamic and creative organizational culture and enhanced remuneration. As part of this movement, managerial talent with experience, knowledge and skills has been lost from the Department. New personnel with the requisite competencies have not been added. The result is that the Department now has limited capacity to:

- develop coherent policy directions for health care, including within the context of federal-provincial relations;
- engage in long-term system-wide planning
- conduct research, especially that which is relevant to standards setting and managerial improvement;
- ensure that quality assurance and risk management activity is taking place within the system;

- develop performance measurement, performance reporting and evaluation frameworks and mechanisms; and
- conduct rigorous financial analysis and to develop financial management systems.

Given the challenges facing the province in the health care field, it is not an exaggeration to state that the Department lacks many of the means to set sound new policy directions and to ensure the efficient, effective and accountable delivery of safe health care services. We would not call the situation a crisis, but there is a clear need to strengthen and revitalize the Department.

A start in the direction of strengthening the Department was made in July, 2000 with the creation of the new position of Assistant Deputy Minister for Regional Affairs to lead the new Division of Regional Affairs. The Division groups a number of related units and activities to better coordinate the Department's overall approach and dealings with the RHAs. The Division includes: Regional Support Services, Financial Services, Capital Planning, Primary Care, Home Care, Long Term Care and Emergency Medical Services and Planning. The Department has also proposed to create another Assistant Deputy Minister position leading a Division responsible for Health Standards, Evaluation and Initiatives. Also proposed is a small Policy and Planning Secretariat covering planning and research, federal-provincial relations, risk management and communications. The Secretariat would report directly to the Deputy Minister. There are also proposals to strengthen the Division led by the Assistant Deputy Minister of Financial Control and Management Accountability.

We recognize that government would be reluctant to spend scarce health dollars on administrative overhead, especially if there might be the perception that the new departmental functions duplicate what is done at the RHA level. However, it is our understanding that the new Divisions in Manitoba Health would be there to set policy and financial frameworks, to support and ensure consistency among the RHAs and to provide oversight of the system. In other words, the Department would not actually develop activities in the fields of standards settings, quality assurance, risk management, performance measurement and evaluation. However, it would possess sufficient "in-house" capacity or contract out for expertise to provide the government and Manitobans with the assurance that these activities are being conducted in a sound and consistent manner throughout the health care system.

Future Directions

The process of regionalization is incomplete, in part because Manitoba Health is still involved with operational matters. According to the Report on Health Care Financial Management and Accountability (the Webster Report), presented to the Government of Manitoba in April 2000, the duplication and overlap between the Department of Health and the RHAs must be eliminated to achieve cost savings and to clarify accountability. The Webster Report also pointed out the anomaly in the Winnipeg region where all but one of the Winnipeg hospitals retained their boards of directors, with their program managers reporting to the WRHA.

A number of joint review committees involving all the relevant stakeholders were proposed in the Webster Report to drive the regionalization process forward. Mention is also made in the Webster Report of an initiative underway involving Manitoba Health and the Regional Health Authorities of Manitoba Inc.

to refine the relationship between the Minister and the RHAs, to identify areas of exclusive and shared accountability and to develop agreed-upon mechanisms of accountability. A rigorous objective evidence-based approach to accountability is seen as the preferred route to follow. The identification of appropriate measurement criteria (of both a clinical and managerial nature) is one of the most challenging and critical functions to be performed by Manitoba Health in collaboration with the RHAs. A collaborative process between Manitoba Health and the RHAs should be developed to monitor performance based agreed criteria.

To implement many of the recommendations of both the Sinclair and the Webster Reports will require a significant investment in sophisticated computer-based clinical and managerial information systems. A joint task force involving the RHAs and Manitoba Health is engaged currently with the development of a provincial IT strategy. Technological support at the level of individual institutions, at the RHA level and within Manitoba Health is clearly inadequate. Investments in information and communications technologies (ICTs) will pay-off in the long-term in greater efficiency, effectiveness and innovation in the health system. They will also contribute to better policy analysis, stronger managerial capacity, the provision of feedback information and early warning signals of emerging issues, and the strengthening of accountability at all levels. There is a particular application of ICTs in conjunction with the proposed Western Canadian Children's Heart Network, which is discussed in a separate chapter.

RECOMMENDATIONS

This chapter has emphasized that the Minister of Health is answerable for the overall performance of the health care system.

The regional model adopted in 1997 delegates significant authority, resources and managerial direction of health care service to the 12 RHA Boards and the Chief Executive Officers who report to them.

The Review Committee recommends that the regionalization process be completed to include all health facilities.

There remain areas of overlap and duplication between the provincial policy determination, standards setting and monitoring role that reduce efficiency and blur accountability. An initiative is underway to more clearly align responsibilities within the provincial-RHA relationship.

The Review Committee urges the completion of this initiative to serve as the basis for clearer direction and sounder accountability framework within the regional health care model.

Manitoba Health is in transition, moving away from a significant role in the direct management of service delivery and towards a new role that focuses on policy frameworks, provincial-wide planning, standards setting, performance measurement and evaluation as a basis for ensuring that all Manitobans have fair and consistent access to competent and safe health care.

To perform in its new role, Manitoba Health needs to be reorganized and to develop new kinds of knowledge and skills among its employees. The Review Committee supports recent actions and further proposals for reform put forward to the Government of Manitoba by the Minister of Health and the Deputy Minister of the Department.

Meaningful accountability in the complex and decentralized structure of regional health care requires the generation and flow of valid, reliable, timely and relevant health care data among stakeholders at all levels within the system. This requirement will involve significant investments in the creation of information technology infrastructure linking the various parts of the health system. It will also require a transformation of the "culture" of the health care system to ensure the greater utilization of data to guide decision-making, with less reliance being placed on political calculations, institutional rivalries and the use of "crises" to leverage additional resources.

The Review Committee supports the work of the provincial taskforce developing a health information technology strategy as a basis for the creation of an information rich context for better informed policy-making, management and risk avoidance.

Chapter 11

Conclusions and Summary of Recommendations

Introduction

The preceding chapters have reviewed the findings and recommendations of the Sinclair Report. In this concluding chapter, we present an overview of what we have learned and provide a summary of the recommendations made in the preceding chapters.

The Review Committee has learned a great deal during its four months of part-time work. We have received an enormous amount of information, presented to us both orally and in writing. All the people whom we met and others who wrote to us were generous in offering their support, encouragement and insight for what was a challenging, at times emotional, but ultimately very important task. We make special mention of the vital contribution of the families at the close of this chapter.

Even with such support and our best efforts, there are aspects of the Sinclair Report that we recognize could have been explored in more depth. Given the steep learning curve that we faced, we accept that there will be some errors of fact and questionable interpretations in our analysis. On the premise that we learn from our mistakes, the Review Committee invites readers to comment on matters where our analysis and recommendations are faulty.

Our primary aim has been to develop recommendations which if acted upon, would prevent a repeat of events similar to those which took place in the pediatric cardiac surgery program at HSC in 1994. We were also concerned with restoring public trust and confidence in the institutions which played a central role in those events.

The task of the Review Committee was different from that of Judge Sinclair in the inquest process. His focus was primarily on the 12 deaths and whether they were preventable. While he could not ignore the wider context in which those events occurred, he was not expected to make recommendations designed to improve the health care system in general. There are, in fact, important observations and lessons about the health care system contained in the Sinclair Report. But it is important to remember that he did not review

all the pediatric surgery programs, the overall functioning of the HSC or that institution's full range of relationships with external monitoring bodies. Since our mandate was to provide forward-looking advice to the Minister of Health on how to restructure the system to prevent similar events from occurring, we were drawn into broader issues.

The Review Committee sees the strong public interest and reaction to the serious and emotional events documented in the Sinclair Report as indicative of the concerns Canadians are feeling about their health care system. Surveys of public opinion tell us that health care reform is the dominant public policy issue today. While a majority of Canadians express satisfaction in terms of their own experiences with the health care system, they also express declining confidence in the future capacity of the system to meet the needs of the population at large. Canadians have more trust in their individual doctors than they do in doctors in general. Nursing care is identified in surveys as the most important factor leading to higher levels of satisfaction.

Levels of public knowledge about the health care system are low, suggesting that governments and health care providers have a communications problem they will need to address in order to restore declining confidence. Fiscal responsibility and accountability have become priority concerns for Canadians. As in other policy fields, governments are only beginning to measure the effectiveness of health care spending. There is strong public support for "report cards" on the quality of physician practice and hospital care as a means to enable individuals to make better informed decisions on how to use the system. Finally, there are growing demands for greater transparency, greater public input, greater responsiveness and strengthened accountability at all levels within Manitoba's complex and dispersed health care system. In an indirect, but powerful way, the Sinclair Report both reflected and reinforced these trends in public opinion towards the health care system.

In presenting our overview, we must begin by reiterating that there have been significant changes in the health care system and its constituent parts since 1995 when Judge Sinclair began the inquest. Other changes have been introduced or are being developed in response to the Sinclair Report. We have tried in our earlier chapters to give credit when changes seemed positive and to offer constructive criticisms and alternatives when changes fell short of what we saw as required.

The causes of the infants' deaths at HSC in 1994 were identified by Judge Sinclair as both individual and systemic in their origins. Individuals within the surgical program, within the medical and administrative structures of HSC and within the external monitoring organizations did not demonstrate the capabilities, the care, the diligence and the commitment to quality care that was expected of them. It is the view of many of the families that the key individuals responsible for the loss of their children and for the subsequent lack of timely, corrective action have yet to pay a serious price for their errors or inactions. In short, the key actors in the tragic events have not been held fully accountable. In contrast, the parents say they have already paid the huge price of losing a child and face a potential life-long emotional burden of coming to terms with that loss. The Review Committee understands the anger and the bitterness of the families. However, we were obliged to tell them that it is not our job to assign blame and liability; those issues must be pursued in other forums like the investigation and inquiry process launched by the CPSM and possible legal actions through the courts.

Beyond the ability and conduct of individuals, there were serious systemic failures involved in the events of 1994. In the health care system, there are many institutions, processes, rules, guidelines, standards, committees and monitoring mechanisms designed to promote competent, safe and ethical care. These mechanisms are both prospective and preventative, as well as retrospective and corrective. Unfortunately, the elaborate system of controls and accountability processes did not function as intended during and after the infant deaths at HSC. There was a failure to ensure the competence of the surgeon. The pediatric cardiac surgery program was restarted without adequate planning and preparation. When problems arose, the concerns raised by nurses and others were not taken seriously. Even when a series of deaths occurred in rapid succession, there was not a timely and appropriate response within the surgical team, the Child Health program, the medical and administrative structures of the HSC, the death review processes of the OCME, and the complaints/investigation processes of the CPSM. To have all the components of the system fail in the case of the death of one child would be disturbing. To have the system fail repeatedly as the death toll mounted over a short period of several months is both shocking and difficult to understand.

To the extent that we understand the breakdown of the system, the explanations are both institutional and cultural in nature. Institutional processes were clearly deficient. But even more important was a medical and health culture which stresses the need to perform flawlessly, and this error-free philosophy creates strong pressures to cover up mistakes rather than to admit them and to seek opportunities for improvement. Health professionals in all fields are intelligent individuals who have studied long and hard to make the "right" decisions and many suffer a strong emotional reaction when they make a mistake which harms a patient, the very person whom they are trying to help. And, health professionals have not always been taught or shown how to cope with this type of situation. Threats of peer review and possible sanctions contribute to the tendency to deny mistakes.

There is a need for a new professional ethos in the health field. It would consist of an acceptance of human fallibility and the inevitability therefore of error. It would involve the recognition that learning occurs not only from our successes, but also from our mistakes and failures. Within the community of health professionals, physicians, and more particularly surgeons, these individuals have been the most confident in their own knowledge and abilities, and therefore, have been the least willing to have their authority challenged. Such an attitude may be understandable, given both the lengthy and specialized education required to become a surgeon and the heroic, sometimes miraculous outcomes of surgeries. However, if the attitude persists that error is unacceptable and that the acknowledgement of mistakes is an admission of incompetence, the opportunity to learn from negative or even disappointing results will be lost. In addition, acceptance of error as a fact of all human activity would make it easier for physicians, nurses, other health care professionals and administrators to say "I am sorry" to patients and their families. Changing the deeply entrenched values of a series of separate, but related professional cultures in the health field will be a slow process, taking decades rather than years, as new generations of physicians, nurses and other professionals enter the field. The process is already underway and it must continue.

The drama and the vividness of the story of the pediatric cardiac deaths leading to the Sinclair Report have served as a "wake up" call and consciousness raising event for health institutions and health professionals in Manitoba. If the various actors within the health care system did not understand previously that

the content and dynamics of health care provision were changing, the Sinclair Report made it clear that a fundamental transformation in the relationships among governments, the self regulating professions, the major health institutions and society was underway. Individual health care providers, health administrators and other institutional actors have been forced to question the key processes which have been relied upon in the past to ensure quality care.

Based upon the above discussion of the changes underway and the greater awareness among health stakeholders about what is at stake, the Review Committee believes that an exact repeat of the events of 1994 in any surgical program is very unlikely. However, there will always be medical errors, the need to learn from them and the need to provide patients with redress mechanisms when they complain.

In the remainder of this closing chapter, the Review committee returns to the four broad areas of concern that we identified in our opening chapter as central to the analysis found in the Sinclair Report. The four sets of concerns were:

- The treatment of the children and their families.
- The individual and collective competence and behaviour of health professionals.
- The organizational context of the hospital in which clinical programs operate.
- The responsiveness and accountability of health institutions and health providers to the wider community.

Because we want to conclude the report with a message to the families, we will discuss these four concerns in the reverse order to that presented above. Our aim is to demonstrate how the preceding chapters of analysis and recommendations represent a coherent and comprehensive response to these four sets of issues. Throughout this report and in these concluding comments, we have sought to be balanced and constructive, focusing more on what needs to be done next than on what went wrong in the past.

RESPONSIVENESS AND ACCOUNTABILITY IN THE HEALTH CARE SYSTEM

Responsiveness and accountability to patients and the public were central themes in the Sinclair Report. Many of its recommendations were intended to enable patients to make better informed choices in accessing and consenting to various types of medical procedures. Other recommendations were designed to strengthen the accountability obligations to the public for individual health care providers, for hospital authorities, for regulatory bodies and for governments.

As Chapter Two of this Report made clear, the accountability picture in the health system is inevitably complicated, blurred and confusing. Greater clarity is possible, but there are definite limits to the potential to streamline and pinpoint responsibility and accountability. In a multi-dimensional and interdependent health care system, authority will always be shared and accountability will be collective, as well as individual. Several types of accountability were identified in Chapter Two. What might appear as overlap, redundancy and a source of confusion, could also provide an extra measure of protection in the event of the breakdown of a specific accountability process since other procedures could provide a backup.

The following points capture the key areas where accountability needs to be strengthened based upon the analysis and recommendations of this report:

- the Minister of Health and the Department of Health need to focus on the strategic level of policy-making and leave operational responsibilities to the RHAs and the individual health institutions;
- to perform in its strategic role, Manitoba Health needs to develop its planning, policy advisory, standard setting, information processing, and evaluation capabilities;
- the process of regionalization, begun in 1999, needs to be completed so that the roles of the Minister/Department of Health and of the RHAs are clarified through a matrix of responsibilities which assigns different types/levels of decision-making primarily to one level;
- lines of authority and accountability have been clarified within the Program Management structure at HSC, but these structural reforms need to be supported by efforts to develop "accountability maps" and to build a culture of both individual and shared accountability;
- HSC needs to develop a formal, written internal disclosure policy to protect individuals who bring forward reasonably held concerns about various kinds of misconduct;
- over the next five years, the Government of Manitoba should monitor developments within provincial health institutions regarding internal disclosure policies and practices and examine the experience with "Whistleblowing" legislation in other jurisdictions;
- HSC has developed an improved policy on informed consent, emphasizing the three key requirements of full disclosure, the highest possible level of understanding and the voluntary nature of the consent. This policy needs to be communicated widely within the institution and could become the model for other hospitals;
- the CPSM has reformed its patient complaint process to make it more accessible and fair, but there is a requirement to create greater public awareness of the process;
- the CPSM has gathered more information on the backgrounds of physicians, but there is a need to work with Manitoba Health to develop a system of "physician profiles" as a way to enable patients and families to make better-informed choices and to promote greater individual physician accountability.

There are other recommendations in this report which will contribute indirectly to improved responsiveness and accountability in Manitoba's health care system, a topic that is a growing public concern.

The Competence of Health Care Providers

The second broad set of issues identified in the Sinclair Report involved the competence and professional relationships among health care providers, particularly between physicians and nurses in the context of the delivery of multidisciplinary programs at the HSC.

The Sinclair Report was critical of the hiring process for the surgeon who lead the pediatric cardiac surgery team at HSC and of the lack of planning and preparation for the restart of the program. The Report was

also critical of the dismissal by the medical leadership of the concerns raised by the nurses and the anaesthetists. As suggested earlier in this chapter, these criticisms reflected and reinforced the growing public perception that physicians are not infallible and do not have a monopoly on the relevant knowledge and skills to deal with illness and poor health. Increasingly, a better educated, better informed and less deferential public is willing to challenge and to debate the judgement of physicians and the courses of treatment they propose.

The Review Committee makes a number of recommendations that relate to the issue of the ongoing competence of health care providers:

- develop more careful recruitment and selection processes, along with strategies to retain physicians and surgeons;
- ensure within HSC and other Manitoba hospitals a sound clinical governance model based upon a number of components that focus responsibility and accountability;
- use multidisciplinary standards committees as the pattern to be used across the province;
- strengthen critical incident reporting policies and practices within institutions;
- strengthen quality assurance and risk management processes;
- develop data bases to monitor surgical programs, beginning with the priority assigned to low volume, high-risk procedures;
- develop the emerging role of the WRHA in dealing promptly with physicians experiencing behavioural problems;
- create greater public awareness of the role of the CPSM within the health care system and the availability of its complaint process to deal with concerns about the conduct of physicians;
- develop and widely distribute a system of "physician profiles" which balance the public's need to know with the rights of physicians to a fair representation of their records of practice;
- develop approaches to the ongoing appraisal of the performance of physicians, to the encouragement of continuing medical education and to the periodic recertification of physicians.

Achieving excellence in clinical practice is a function of many factors that go beyond the technical competence of individual physicians. Identifying deficiencies in clinical performance early and offering support to physicians encountering problems is much preferred over dealing with mistakes through the disciplinary process.

Most of the emphasis in the Sinclair Report was on the continuing competency of physicians but attention also needs to be paid to the matter of the competencies of the present and future generations of nurses. As was mentioned in earlier chapters of this Report, the inquest process revealed that nurses were not treated as full and equal members of the surgical team involved with the pediatric surgery program at HSC. Changes made to the hospital's organizational structure in 1994 were also seen to have reduced the status of nurses within the institution. More generally, the Sinclair Report portrays nurses as occupying a subordinate position within the health care system.

The Sinclair Report was critical of the lack of formal recognition of the unique, expanded and critical role that nurses now play within the health care system. During the past several decades, nursing education has changed greatly to incorporate new knowledge and skills. The scientific, research, managerial and ethical components of nursing education have been expanded and strengthened. Advanced levels of nursing education and new fields of nursing specialization have come into existence. Many more nurses today go beyond their first degree to obtain additional education and training. As a group, nurses have placed growing emphasis on life-long learning, regular evaluation of knowledge and skills, and the duty to report on the performance of their professional colleagues. The scope of practice of nursing has widened as new fields emerge and as nurses assume duties previously assigned to physicians or other professionals. Along with these important changes, it remains the fact that nurses generally have the most contact with patients. Nurses are with patients around the clock. They are expected to develop the knowledge, skills, initiative, judgement and sense of responsibility to mange complex patient problems and to perform numerous administrative tasks.

Despite these changes to nursing education and to nursing practice, there has been reluctance by many (but definitely not all) physicians and hospital administrators to accept nurses as professional equals with a distinctive, crucial contribution to make to the care process. Formal recognition of the changed role of nurses within the structures of health care institutions has been difficult to achieve, but even more challenging has been changing long-established attitudes and stereotypes about the present and potential future roles of nurses. There is still the residual attitude that nurses should see, listen and be silent. On the basis of their professional education and career experiences, some nurses (mainly those from earlier generations) still engage in self silencing, both out of deference towards physicians and out of concern for their career prospects.

The Review Committee has made a number of recommendations to deal with the place of nurses within HSC and the broader health care system. The recommendations include: the treatment of nurses as equals on program management teams; the use of the Nursing Practice Council to obtain the input of nurses into hospital decision-making; the development of an internal disclosure policy for HSC to protect nurses when they raise legitimate concerns; the participation of nurses on standards committees; and the transformation of organizational cultures to ensure that nurses are not treated by physicians and administrators as undertrained subordinates whose concerns can be dismissed as ill-informed or emotional responses to tragic outcomes.

A further step to upgrading the place of nurses within the Manitoba health care system would be the early proclamation of the new *Registered Nurses Act* (Bill 36). The *Act* has passed all stages within the Legislature and awaits royal assent and proclamation. This is a decision which rests with the Government of Manitoba. For a number of reasons, the Review Committee believes that the process of bringing the new *Act* into force should take place as soon as possible.

Bill 36 would create a new regulatory framework for nursing in the province to replace an outdated *Act* first passed in 1980. The bill contains a great many provisions, however, only those most germane to the issues of the competencies of nurses and their place in the health care system will be mentioned here. Bill 36 would allow for the recognition of the expanded and more specialzied nature of nursing roles, in part by

allowing for more flexible scope of practice guidelines. Regulations pursuant to the *Act* (were the bill to be proclaimed) would identify the legitimate practice of appropriately qualified nurses to include screening and diagnostic tests, prescribing designated categories of drugs and performing minor surgical procedures.

Corresponding to expanded responsibilities for nurses are increased accountability requirements and stronger requirements for demonstrated continuing competence. In terms of accountability, there is an emphasis on increased transparency and public representation in the hearing process involving complaints against nurses. In terms of professional competence, Bill 36 provides for the establishment of a continuing competence program for Registered Nurses. The program includes the conduct of practice audits and the requirement for members to participate in professional development programs to update their knowledge and skills. Bill 36 also imposes a statutory duty on Registered Nurses to report unfitness to practice on another member based on physical or mental condition.

The Review Committee believes that a modernization of the regulatory framework for the nursing profession is overdue and that Bill 36 strikes the appropriate balance between protection of the public interest and the recognition of the need for autonomous, responsible nursing practice. The Review Committee can only speculate on the reasons for the delay in proclaiming Bill 36, but we recommend that action be taken as soon as possible to move it into law.

The Review Committee also wishes to compliment and support the initiative of the College of Physicians and Surgeons and the Manitoba Association of Registered Nurses for the agreement reached in December 2000 titled "Guidelines for Shared Competencies and Delegated Physician Services." This agreement between the two leading regulatory bodies in the health field is intended to assist nurses, physicians and health care institutions to make appropriate and safe decisions respecting overlapping scopes of practice and the delegation of physician services to registered nurses. This is an important step forward in terms of professional collaboration and one which will benefit Manitobans by enabling more flexible and cost effective delivery of health services.

THE EXPERIENCES OF PATIENTS AND FAMILIES

The Sinclair Report documents a disturbing story of 12 families consenting to surgery on their children without being provided full information about such crucial matters as the risks involved, the inexperience of the surgeon, the problems in the pediatric cardiac surgery program, and the fact that a suspension and review of the program had taken place. Some of the families appear to have been given the news of the death of their child in an insensitive and uncaring manner. In their moments of crisis, some parents felt all alone. Full explanations for the causes of death were not always provided. Autopsy reports arrived late and were written in language that was difficult for some families to understand. Only by hearing about it in the media did the families learn that the pediatric cardiac surgery program had been suspended, and that an inquest had been called. We repeat these facts because our meetings with 10 of the 12 families brought home to us, in a way that no report could, the deep sense of grief and betrayal felt by the parents who lost their children.

Judge Sinclair concluded his report with the following passage:

> "From all the facts and evidence that has been uncovered, there is one thing that stands out, the deaths of these children were not the result of any failing on the part of the parents. There was nothing that these parents did that they ought not to have done. There was nothing that they did not do that they should have done. Faced with the situation that each of them saw, they did what they believed was best for their child and they acted on the basis of the best information they were able to obtain." (Sinclair Report, page 502)

The Review Committee agrees. We recognize that nothing we state or recommend can erase their sense of loss and betrayal.

The Review Committee made a commitment to the families that the primary aim of our recommendations would be to prevent a repeat of anything like the tragic events of 1994. Accordingly, we have made a series of recommendations throughout this Report to provide better protection for patients and families and to ensure they are always treated with the respect and dignity they deserve. Among the recommendations which support these aims are the following:

- stricter policies on informed consent and improved physician-patient communication within the consent process;
- the publication and easy availability of physician profiles to enable patients to make better-informed choices about physicians and agreements to particular medical procedures;
- the publication of a guide to Manitoba's health services covering the basic information needed to make use of the health system and to lodge complaints;
- the development within health care facilities of internal disclosure policies to provide protection for employees and others working in the facilities who raise reasonably held concerns about the treatment of patients;
- a strengthening of the emerging role of the Winnipeg Regional Health Authority in dealing in a timely manner with physicians with personal conduct problems;
- the development of a more visible, proactive complaint/investigation process by the College of Physicians and Surgeons of Manitoba to deal with patients' concerns about medical practice and patient case management; and
- the development of an integrated program of financial assistance and support services for patients and families required to travel out of province to receive medically necessary treatment.

Procedural safeguards are important, but they will work well only on the basis of a health care culture which is committed to quality, the reduction of mistakes and the willingness to use untoward events to achieve individual and organizational learning.

FINAL THOUGHTS

We began this report by calling attention to the complex and dynamic nature of the health care system. If the health care system once sailed along on relatively calm waters, it now seems to face conditions of permanent "white water" involving constant review and change. During recent decades, there have been few, if any, opportunities in the health system for individuals and institutions to fully absorb one wave of change before another wave crashes down upon them.

Consideration of this report and implementation of its recommendations will absorb further time and energies of the dedicated professionals and others who work within the Manitoba health care system. There are limits, not easily specified, to the frequency, scope and speed of changes that the health care system can successfully achieve during any given time period.

There are also financial limits which require that informed choices be made and that budgetary priorities be set. We have not been as successful as we hoped we would be in identifying the costs of our recommendations. We recognize that creating an elaborate system of preventative safeguards and accountability mechanisms would have direct and significant financial implications, which the institutions involved have the expertise to calculate. Less easy to calculate are the indirect costs, such as the impacts of new controls on the motivations and behaviour of key players within the health care system. All the available reports suggest there are savings to be found within the health care system which could pay for the reforms recommended in this report. On the other hand, there are also significant unmet needs and public expectations that place upward pressure on health care spending.

Clearly, improving the quality of health care services has to be the primary goal. Spending scarce health care dollars on the prevention of mistakes and the enforcement of accountability is justified up to a point, but making a precise cost/benefit analysis is difficult and questionable from an ethical standpoint. There is also the concern that should the Government of Manitoba move ahead of other jurisdictions in establishing regulatory mechanisms like physician profiles and whistleblowing laws it may face a further disadvantage in terms of the recruitment and retention of health care professionals. The Review Committee is convinced that future changes in health care will be in the direction forecast in our recommendations and we would be pleased to see Manitoba pioneer some of those changes. But it would be more advantageous if the Province worked with other jurisdictions in adopting such reforms.

In our penultimate paragraph we wish to speak to the families who, among all the groups and individuals we met, had the most profound impact on our understanding and thinking concerning the right of all Manitobans to competent and safe medical care and to be treated with respect and dignity. We have dedicated this report to your children and to you in the hope that there will be some comfort in knowing that your great loss will potentially bring benefits to future generations of children and families who will receive the quality of health care they deserve. We would understand if some or all of the families felt that this Report was not critical enough of the people and organizations involved with the tragic events of 1994 and that the recommendations we make do not go far enough to prevent similar problems in the future. Within the mandate we were given, we have tried sincerely to uphold our commitment to honour the memory of your children and your loss.

We urge the Government of Manitoba and all the other stakeholders in the health care system to give serious consideration to the recommendations in this report and to act expeditiously on those which are considered sound. To encourage action and accountability for results, we make one final recommendation.

Within a year of the release of this report, the Minister of Health, with the support of the Department of Health, prepare a status report on actions taken to date within the various institutions to implement the recommendations. This status report should be made public and be tabled in the Manitoba Legislature.

A summary of the recommendations of the Review and Implementation Committee and of the Pediatric Cardiac Surgery Inquest Report follows.

Summary of Committee Recommendations

The Review Committee recommends that steps be taken to expedite and better coordinate the physician recruitment and selection process among the organizations involved so that promising candidates are not lost.

The Review Committee recommends that contracts and letters of appointment of physicians should require a notice period for departures and that any breach of this requirement be included in letters of reference for positions elsewhere.

The Review Committee recommends that formal search committees be used for all hospital hirings. Such search committees should be multidisciplinary including physicians, nurses and other relevant health personnel.

The Review Committee recommends that a number of strategies be used in the recruitment and selection process to determine the willingness and demonstrated capacity of physicians and surgeons to work in a team context.

The Review Committee considers the proposal to observe all surgical candidates at work to be impractical in terms of time and expense. The Review Committee recommends that "junior" surgeons "shadow" their senior colleagues and that formal mentoring relationships be developed.

The Review Committee recommends that Manitoba Health identify anomalies in the fee schedules for physicians and surgeons that do not support provincial health priorities and seek approval for a bargaining strategy to correct those anomalies in advance of fee negotiations with the Manitoba Medical Association.

The Review Committee recommends that all health care institutions in the Province have written orientation policies and programs and that participation in such programs be mandatory for all new personnel, including physicians.

The Review Committee recommends that Manitoba Health and the WRHA review the staffing levels for pathologists at HSC in light of the issue of timely autopsy reports raised in the Sinclair Report. This recommendation must be acted upon in conjunction with the recommendation in Chapter Seven on possible changes to the death review process conducted by the OCME.

The Review Committee recommends that each Program Management division develop an "accountability map" which designates responsibilities and traces the lines of reporting back to the Chief Operating Officer of HSC.

The Review Committee recommends the further implementation of the Program Management model at HSC through the clear assignment of costs and the generation of performance information along program lines.

The Review Committee recommends that on a cyclical basis, the HSC evaluate the performance of its program teams to ensure that they are functioning on the basis of shared leadership and the full utilization of the disciplinary expertise of all members.

The Review Committee recommends that the HSC examine means to encourage more physicians to participate in courses on teamwork and conflict management. This would involve, in part, examination of alternative remuneration arrangements for physicians.

The Review Committee commends HSC authorities for the creation in January 2001 of the Nursing Practice Council and recommends that the Council become a key source of advice on nursing practice issues throughout the institution.

The Review Committee recommends that the leadership of HSC give serious and sustained attention to changing the climate and culture of the institution as a more prominent part of an integrated strategy for organizational change.

The Review Committee recommends that part of the cultural change process within HSC involve a recognition of the inevitability of medical errors and other untoward events and an acceptance of the need to learn from such developments.

The Review Committee was impressed with the new critical incident reporting policy within HSC. We recommend that the policy be strengthened by including protection against reprisal for individuals who raise legitimate, reasonably-based concerns.

The Review Committee believes that the current structure for quality assurance within HSC – which combines line responsibility with corporate promotion and monitoring – offers the best potential for ensuring quality concerns are integrated into everyday decision-making. The Review Committee recommends that the HSC, working with the appropriate WRHA staff, develop a multi-year cycle of quality audits of specific clinical and support service areas.

The Review Committee supports and recommends funding for the proposed Child Health Program Quality Initiative.

The Review Committee believes that the elements of a sound risk management system exist at HSC. The Review Committee recommends that stronger risk management strategies and better information on different types risk be developed.

The Review Committee recommends that HSC authorities explore ways to make the patient experience less intimidating and more supportive.

The Review Committee recommends that the Patients' Representative Office at HSC should be more visible, should act as a neutral intermediary between patients and hospital personnel, should track patient complaints over time, and should report directly to the Vice-President and Chief Nursing Officer.

The Review Committee recommends that the accountability of the Chief Operating Officer of HSC to the WRHA Board of Directors be reviewed to ensure that the Board is setting broad policy direction for the hospital and is providing sufficient scrutiny of hospital operations to assure itself that competent, safe, effective and ethical care is being provided.

The Review Committee commends HSC authorities for their continuing efforts to improve its informed consent policy and to educate employees about its content and requirements. The Review Committee recommends that the informed consent policy at HSC become the model for adoption within RHAs and/or health facilities throughout the Province.

The Review Committee does not support the concept of a Handbook of Patients' Rights for the reasons stated in this chapter. Instead, the Review Committee recommends that Manitoba Health should produce and distribute "A Guide to Manitoba's Health Services." The proposed guide would contain information such as: the principles of *The Canada Health Act*, a listing of the health services which are insured and not insured within the Province, the right of patients to informed consent, the provincial policy on out-of-province travel for medically necessary care, an outline of the delivery structure for health care services and an office location, telephone number and web site where additional information and answers to questions can be found.

The Review Committee recommends that all RHAs and/or facilities produce a similar guide to services and a contact point for questions and complaints.

The Review Committee endorses the development and publication of physician profiles that balance the public's right to know with protection against unfair damage to the reputations of physicians.

The Review Committee endorses performance measurement and performance reporting on surgical and program outcomes. However, it cautions that there are inherent analytical problems with such activities and significant financial costs involved in creating the computer-based information structures required. Manitoba Health should play a lead role in collaborating with other stakeholders in the health system to establish priorities in this area.

The Review Committee recommends that the proposed "Guide to Manitoba's Health Services" indicate clearly that travel out-of-province to receive medically necessary services is not an unqualified right. The Guide should provide a contact location for information on conditions of eligibility and the nature of the financial support for out-of-province travel.

The Review Committee recommends that HSC and other hospitals in Manitoba develop policies on internal disclosure as part of a broader strategy to promote cultures and climates of openness and creative-problem solving in which individuals can raise legitimate and reasonably-based concerns without fear of reprisal.

The Review Committee recommends that Manitoba Health monitor the development of internal disclosure policies and their operations within hospitals and the experience with whistleblowing laws in other jurisdictions. If after five years, there are continuing problems and complaints involving a lack of responsiveness by hospitals to concerns raised by their staff, Manitoba Health should at that point consider the adoption of a *Whistleblower Act* for the health field or the public sector in general.

The Review Committee recommends that Manitoba Health through the RHAs should direct hospitals to notify the OCME of "significant changes" to programs and of program reviews prompted by hospital-related deaths.

The Review Committee supports the OCME efforts to improve tracking of hospital-related deaths, but that further steps in this direction should be integrated with the development of a computer-based information infrastructure for the overall health system.

The Review Committee recommends a review of the role, number and location of MEIs based upon the outcome of the current fee dispute between the Department of Justice and the Manitoba Medical Association representing the MEIs.

The Review Committee recommends no change in the employment status of pathologists.

The Review Committee endorses the recommendation that the OCME develop guidelines for pathologists on the conduct of autopsies to ensure that all relevant perspectives are included.

The Review Committee recommends that the OCME conduct a process analysis of the steps involved with its investigations and autopsies to determine whether a "re-engineered process" could maximize productivity and expedite the autopsy process.

The Review Committee recommends that the CPSM adopt a more pro-active education strategy to promote public awareness of the role that the College plays within Manitoba's health care system, including its role in dealing with complaints about physician behaviour and its disciplinary powers.

Such a strategy would include more widespread distribution and more prominent display of brochures describing the College's role and the rights of patients under its Complaints/Investigation procedure. It

would involve College Officers appearing in educational forums, before community groups, at conferences, on the media and in other venues to describe and explain the role of the College.

The Review Committee recommends that the CPSM Code of Conduct be modified to include a duty on the part of physicians to inform patients and others about the role of the College and the availability of the complaint process.

The CPSM Code of Conduct has sections dealing with the responsibilities of physicians to the profession, to the College and to society, but there is not a duty to promote public awareness of the College and its procedures for handling complaints. The other responsibilities imply a duty to inform patients about the College and this should be recognized in the Code.

The Review Committee recommends that the CPSM work with Manitoba Health and other interested groups to develop a system of "physician profiles" describing the education, experience, training, awards, disciplinary history and other information deemed relevant for each physician practicising in Manitoba. In the context and format for physician profiles, a balance must be found between the public's right to know and easy access to information with the right of physicians to a measure of privacy and to an accurate, balanced and fair interpretation of their history of medical practice.

Several questions could be raised about the recommendations that the CPSM play a larger role of public education. The profession might see this as more appropriately the responsibility of Manitoba Health and perhaps of the Regional Health Authorities. However, the CPSM is not the Manitoba Medical Association, the professional organization which represents doctors. The CPSM has been endowed with public authority to allow physicians the privilege of self-regulation and with this authority comes an obligation to promote public awareness of its role. This educational role will be shared with other bodies in the health system and there should be discussions with Manitoba Health and others about coordinating and perhaps cost sharing in the field of public education.

The Review Committee recommends that the CPSM proceed to develop a more formal program of Continuing Medical Education for its members.

The Review Committee recommends that the CPSM adopt the Physician Achievement Review process used in Alberta to incorporate both peer review and patient input into the evaluation of physician performance.

The Review Committee recommends that the CPSM, in consultation with Manitoba Health, develop over the next five years a program for the periodic recertification of doctors as a means of ensuring quality practice and maintaining public confidence and trust in the profession.

The medical profession today definitely faces a more challenging environment than in the past. There are pressures for more direct patient and public involvement and for more accountability for physicians, both individually and collectively. The process of professional self-regulation has been reformed, but more needs to be done to ensure timely responses to identified problems in clinical practice. In addition to ensuring

physicians are qualified to practice at the beginning of their careers, the CPSM must strengthen its commitment and support for the concept of lifelong learning. Identifying and tackling serious or persistent clinical problems in a timely manner should be emphasized over dealing with problems after they enter the complaints process.

The Review Committee recommends that for the immediate future, there should be no restart of the pediatric cardiac surgery at HSC. Pediatric cardiac surgery programs are costly to support in terms of programming funding. Fiscal resources that would be utilized for a Manitoba pediatric surgery program should be redirected to support the WCCHN.

The Review Committee recommends that the Province of Manitoba continue to support and play a lead role in the development of the WCCHN as basis for providing high-quality pediatric cardiac surgery to Manitobans.

The Review Committee recommends that in the development of the WCCHN that attention be paid to the needs of families in terms of the concerns raised above. Patient experience and patient satisfaction should be a larger component of the formal in-depth evaluation scheduled to take place several years after the launch of the program.

The Review Committee recommends that the WCCHN be seen as a possible model for extension of collaboration with pediatric surgical programs in Eastern Canada and for other specialty programs where Manitoba could benefit from participating in interprovincial programs.

The regional model adopted in 1997 delegates significant authority, resources and managerial direction of health care service to the 12 RHA Boards and the Chief Executive Officers who report to them.

The Review Committee recommends that the regionalization process be completed to include all health facilities.

There remain areas of overlap and duplication between the provincial policy determination, standards setting and monitoring role that reduce efficiency and blur accountability.

An initiative is underway to more clearly align responsibilities within the provincial-RHA relationship.

The Review Committee urges the completion of this initiative to serve as the basis for clearer direction and sounder accountability framework within the regional health care model.

Manitoba Health is in transition, moving away from a significant role in the direct management of service delivery and towards a new role that focuses on policy frameworks, provincial-wide planning, standards setting, performance measurement and evaluation as a basis for ensuring that all Manitobans have fair and consistent access to competent and safe health care.

To perform in its new role, Manitoba Health needs to be reorganized and to develop new kinds of knowledge and skills among its employees.

The Review Committee supports recent actions and further proposals for reform put forward to the Government of Manitoba by the Minister of Health and the Deputy Minister of the Department.

Meaningful accountability in the complex and decentralized structure of regional health care requires the generation and flow of valid, reliable, timely and relevant health care data among stakeholders at all levels within the system. This requirement will involve significant investments in the creation of information technology infrastructure linking the various parts of the health system. It will also require a transformation of the "culture" of the health care system to ensure the greater utilization of data to guide decision-making, with less reliance being placed on political calculations, institutional rivalries and the use of "crises" to leverage additional resources.

The Review Committee supports the work of the provincial taskforce developing a health information technology strategy as a basis for the creation of an information rich context for better informed policy-making, management and risk avoidance.

Within a year of the release of this report, the Minister of Health, with the support of the Department of Health, prepare a status report on actions taken to date within the various institutions to implement the recommendations. This status report should be made public and be tabled in the Manitoba Legislature.

THE PEDIATRIC CARDIAC SURGERY INQUEST REPORT
CHAPTER 10 – FINDINGS AND RECOMMENDATIONS
SUMMARY OF REPORT RECOMMENDATIONS

Page 469

#1

It is recommended that: The Health Sciences Centre establish a medical staff recruitment process for senior or specialized positions within the hospital that has as its main priority the creation of a mechanism that results in the best possible candidate being hired or appointed.

Page 470

#2.

It is recommended that: The Manitoba government and the Manitoba Medical Association adjust the Manitoba Doctor's fee schedule to allow for the payment of compensation to pediatric cardiac surgeons that does not stand in the way of the effective recruiting of, and maintenance of, pediatric cardiac surgeons in Manitoba. The fee schedule should reflect the fact that pediatric cardiac surgeons are as highly trained as adult cardiac surgeons; that because of lower case load, pediatric cardiac surgeons will perform fewer operations than adult cardiac surgeons; and that the operations that pediatric cardiac surgeons perform will be just as, if not more, complex than adult cardiac operations.

Page 471

#3

It is recommended that: If a Pediatric Cardiac Surgery Program is re-established at the Health Sciences Centre, it have clear written lines of authority and responsibility. Efforts must be made to ensure that program members understand these lines of authority. This is of particular importance in a multidisciplinary program.

Page 472

#4

It is recommended that: If a Pediatric Cardiac Surgery Program is re-started at the Health Sciences Centre, overall supervision for the program should be the responsibility of a single Department Head – logically the head of Pediatrics. The head of Pediatrics can more easily supervise a program that has as its focus pediatric cases. Staff providing service to any revamped Pediatric Cardiac Surgery Program should be primarily assigned to the program and be accountable to the head of Pediatrics through their appropriate department head or line manager for their performance. In particular the head of Pediatrics should also have responsibility for monitoring the surgical performance for of the pediatric cardiac surgeon through the assistance of the head of Pediatric Surgery and the head of Pediatric Cardiology. The head of Pediatrics should ensure that the surgeon, the head of Pediatric Cardiology and the head of Pediatric Anesthesia have a plan to phase in the surgical program. In addition, the program should be monitored closely, with regular reports going to the head of Pediatrics.

Page 475

#5

It is recommended that: The Health Sciences Centre develop protocols for providing orientation and support to all new staff and staff moving into new positions. This should be done even when the appointment is to an Acting position.

Page 475

#6

It is recommended that: Any re-established Pediatric Cardiac Surgery Program involve all units that would be affected by the program in the development of appropriate protocols. Such protocols should include a requirement that the entire team, including those individuals responsible for post-operative care, be fully prepared before the program moves to higher-risk cases or new procedures.

Page 476

#7

It is recommended that: Any restart of the Pediatric Cardiac Surgery Program be initiated only after the relevant department heads jointly review staffing levels and assure themselves that they are appropriate to avoid overwork and fatigue and maintain appropriate skill levels. This applies to every discipline involved in the program.

Page 478

#8

It is recommended that: The Health Sciences Centre restructure its Nursing Council to allow nurses to select its membership and to give it responsibility for nursing issues within the hospital. The Nursing Council should have representation from on the hospital's governing body and be responsible for monitoring, evaluating, and making recommendations pertaining to the nursing profession within the hospital and for nursing care. The Council should also serve as a vehicle through which nurses could report incidents, issues, and concerns without risk of professional reprisal.

Page 479

#9

It is recommended that: The Health Sciences Centre establish a clear policy on how staff is to report concerns about risks for patients. This policy must ensure that there is no risk to the person who is making the report. It should be clear that every staff member to whom they are to present such reports.

Page 479

#10

It is recommended that: The Province of Manitoba consider passing "whistle-blowing" legislation to protect nurses and other professionals from reprisals stemming from their disclosure of

information arising from a legitimately and reasonably held concern over the medical treatment of patients.

Page 481

#11

It is recommended that: The Department of Health of the Manitoba Government prepare a patient's rights handbook that among other things, deals with the issue of informed consent. That handbook should clearly set out that a patient and a parent acting on behalf of a minor have a number of rights, including, but not limited to:

- The right to be fully informed before giving consent to medical treatment;
- The right to information about a surgeon's experience in performing a particular procedure, as well as the experience of the hospital and/or surgical team;
- The right to a second opinion;
- The right to an out-of-province referral in certain circumstances, including where the patient or parent chooses to have a procedure performed by a surgeon or institution with more appropriate experience and where the surgeon or institution in Manitoba lacks the same experience; and
- The right to have and out-of-province surgeon perform the procedure in Manitoba, provided that there is a surgeon willing and able to do the procedure here.

Page 481

#12

It is recommended that: The Department of Health direct Manitoba hospitals to require that, as part of their obligation to obtain informed consent from a patient, hospitals have a positive obligation to provide to a patient, or parent on behalf of a minor, information about:

- The right to information about a surgeon's experience in performing a particular procedure, as well as the experience of the hospital and/or surgical team;
- The right to a second opinion;
- The right to an out-of-province referral in certain circumstances, including where the patient or parent chooses to have a procedure performed by a surgeon or institution with more appropriate experience and where the surgeon or institution in Manitoba lacks the same experience; and
- The right to have and out-of-province surgeon perform the procedure in Manitoba, provided that there is a surgeon willing and able to do the procedure here.

Page 481

#13

It is recommended that: The Health Sciences Centre review its policies on consent and communication with families. All information that is germane to a child's care or to decisions that must be made about a child's care should be provided to those from whom consent is being obtained.

In particular, the policy on consent must make it clear that the medical staff treating a patient must be forthright and truthful in disclosing all relevant information to the patient or representative before the procedure in question. The fact that the surgeon has not performed a particular surgical procedure on his or her own in an unsupervised setting in the past must be disclosed.

Page 482

#14

It is recommended that: The Government of Manitoba establish a policy for the payment for counsel for families granted standing at inquests, taking into account the following factors:

1. The length of proceedings.

2. The complexity of the issues.

3. Whether or not the costs of family involvement in the proceedings would be prohibitive to the applicant.

4. Whether or not the presiding judge so recommends on application by the family.

Page 483

#15

It is recommended that: The Government of Manitoba pay the entire legal costs of the families involved in these proceedings.

Page 486

#16

It is recommended that: The Office of the Chief Medical Examiner develop a protocol requiring hospitals to inform that Office of significant changes in the delivery of medical services, such as program slowdowns and shutdowns, as well as any hospital-related deaths that cause the hospital to undertake a program review.

Page 486

#17

It is recommended that: The Office of the Chief Medical Examiner maintain a database of hospital deaths, which would track in-hospital deaths and causes of death on a weekly and monthly basis.

Page 486

#18

It is recommended that: As part of their investigation into a patient's death, the Chief Medical Examiner's Investigators conduct a preliminary interviews of nursing and medical staff who had been involved in the patient's death.

Page 486

#19

It is recommended that: For CME cases the Chief Medical Examiner arrange to have autopsies performed by a pathologist not affiliated with the hospital where the operation had been performed, unless it is unreasonable or impossible to do so due to distance, time, or expenses.

Page 486

#20

It is recommended that: The Chief Medical Examiner develop guidelines for pathologists to follow in obtaining information before performing an autopsy in CME cases. These guidelines should not place over-reliance on anyone whose involvement might have contributed to the death of the patient.

Page 486

#21

It is recommended that: The Office of the Chief Medical Examiner establish reasonable timelines to complete autopsies, prepare and forward preliminary results and complete the final reports, including the completion of necessary laboratory work.

Page 487

#22

It is recommended that: The Office of the Chief Medical Examiner insist on compliance with reasonable timelines for the preparation and delivery of autopsy results.

Page 487

#23

It is recommended that: The HSC and other hospitals amend their autopsy consent forms. The forms should make it clear that the hospital might wish to retain organs and other specimens from the bodies of deceased patients. Families should have the option of withholding such consent, while still consenting to the autopsy itself.

Page 498

#24

It is recommended that: The Province of Manitoba consider legislation that requires hospitals throughout Manitoba to establish appropriate quality assurance and risk-management programs that accord with the principles and suggestions contained in this report, and that legislative protection be granted to the discussions that form part of those processes, provided that the right of patients and their families to full disclosure of what has occurred to them during the course of treatment is not compromised.

Page 498

#25

It is recommended that: The HSC, in conjunction with the Winnipeg Regional Health Authority, develop a quality assurance and risk management program employing the principles and suggestions contained in this report.

Page 498

#26

It is recommended that: The HSC exclude doctors who have been involved in a case that is under review by any of the hospital standard committees from participating in the decision-making process relating to such a review.

Page 498

#27

It is recommended that: The HSC Department of Surgery develop an appropriate database for all surgical procedures, but particularly for pediatric cardiac surgical operations. The database should include information such as cross-clamp times, cardiopulmonary bypass times, total circulatory arrest times, amount of blood products used and such other relevant information as would allow for the proper monitoring of surgical trends within a given program or for a particular surgeon.

Page 498

#28

It is recommended that: Pediatric cardiac surgical data be collected in a way that makes it possible to compare Winnipeg procedures with those preformed in other centres.

Page 498

#29

It is recommended that: The HSC establish a clear policy on how staff is to report concerns regarding risks for patients. This policy must ensure that there is no personal or professional jeopardy to the person who is making the report. It should be clear to every staff member to whom they are to present such reports.

Page 498

#30

It is recommended that: The HSC Administration ensure that all staff members are made aware of their responsibility to use incident reports and fully chart problems with the process of delivery of care and any complications in the outcome of care.

Page 500

#31

It is recommended that: The HSC, the Winnipeg Regional Health Authority and the Manitoba Department of Health pursue discussions with provinces in Western Canada for the development of a Western or Prairie regional Pediatric Cardiac Surgery Program.

Page 500

#32

It is recommended that: A provincial Pediatric Cardiac Surgery Program be developed at the HSC that is limited to undertaking lower and medium-risk procedures, but can undertake more complex procedures in conjunction with a regional pediatric cardiac surgery centre.

Page 500

#33

It is recommended that: The Province of Manitoba develop a financial assistance package for families required to travel out of province for surgical treatment of family members. The package should ensure that family members are in no worse a financial position than if the treatment had been provided in Manitoba.

Page 500

#34

It is recommended that: As a part of any planned restart of the Pediatric Cardiac Surgery Program, the post-operative care of pediatric cardiac patients be centralized in a single intensive care unit.

Page 501

#35

It is recommended that: The College of Physicians and Surgeons of Manitoba revamp its policies and procedures so that in the future investigations and disciplinary proceedings no longer depend on whether or not a formal complaint has been filed with the College.

Page 501

#36

It is recommended that: The College of Physicians and Surgeons review this report to determine if there are grounds for undertaking disciplinary proceedings against any of the medical professionals involved in the care of any of the 12 children whose deaths were the subject of these proceedings.

Appendix A

The Review and Implementation Committee for the Report of the Manitoba Pediatric Cardiac Surgery Inquest

Paul Thomas is a Professor in the Department of Political Studies at the University of Manitoba and has taught at the University since 1969. He holds a Bachelor of Arts (Honours) and Masters Degree from the University of Manitoba and a PhD from the University of Toronto. Thomas was the co-author of the best-selling textbook Canadian Public Administration and is the author of more than 50 journal articles and book chapters on various topics. His current research deals with leadership in the public sector. Thomas has been a consultant to both federal and provincial governments and to several royal commissions and task forces. He has received the Lieutenant Governor's Medal for Excellence in Public Administration awarded by the Institute of the Public Administration of Canada (Manitoba Chapter).

Gail Bagnall has been the Superintendent/Chief Executive Officer of Lord Selkirk School Division #11 since 1993. She has held senior management positions in the Department of Education and Training, Transcona Springfield School Division and St. James School Division. Bagnall has a Bachelor of Arts (Honours) and a Master of Education Degree and has served on a variety of provincial and national committees and associations. Currently, she serves as co-chair of the 2003 Western Canada Summer Games; member of the Board of Governors, Red River College; member of the Interlake Regional Health Authority Interagency Committee, the RCMP Inter-organizational Committee and a number of Oakbank community and cultural initiatives.

Helga Bryant is currently the Vice-President of Acute Care and Diagnostic Services for the Brandon Regional Health Authority. Bryant graduated with a registered nursing diploma and worked general duty of surgical units for a number of years prior to completing a Critical Care course and working in the Brandon Regional Health Centre Intensive Care Unit. In 1993, Bryant received a Bachelor of Science Degree in Nursing and in 1997 a Masters of Science in Health Care Administration. In February 1998, she assumed the position of Acute Care and Diagnostic Services with the Brandon Regional Health Authority. Bryant has received the Westman YWCA Woman of Distinction Award and serves on a board within her church.

Appendix A

Appendix B

Advisory Committee Members and Other Participants

Linde Feakes
Barbara Petkau
Walter Petkau
Danica Terziski
Sara Tena
Benedict Capilli
Donna Still
Shirley Still
Saul Simmonds

Laurie Maguire
Barbara Maguire
Richard Shumila
Lana Perchaluk
Martin Corne

Emily Ulimaumi
Mary Kay Pameolik
Sheena Goyal
Vipan Goyal
Charlotte Caribou
Morris Dell
Paul Walsh
Susan Elenduik

Carol Youngson
Joan Borton
Carol Bower
Irene Hinam
Debra Armitage

Colleen Suche
Susan Hagemeister
Ross Hagemeister

College of Physicians and Surgeons of Manitoba
- Dr. Eric Stearns
- Dr. Wayne Kepron
- Dr. Bill Pope
- Doreen Kelly

Manitoba Association of Registered Nurses
- Betty Frost
- Susan Neilson

Winnipeg Regional Health Authority
- Dr. Brian Postl
- Jan Currie

Health Sciences Centre

John Horne
Heather Crawford
Karin Dixon
Dr. Bryan Magwood
Susan Shallcross
Dr. Reeni Soni
Lea Legge
Dr. Michael Moffatt
Terry Parkinson
Catheryn Martens
Dr. Thambirajah Balachandra
Dr. Luis Oppenheimer

Office of the Chief Medical Examiner

Dr. Thambirajah Balachandra
Johanna Abbott
Dr. Charles Litman
Dr. Jon Younes

Coalition for Improved Access to Physician Practice Information

Barbara Wiktorowicz
David Steen
Glen Bergeron
Ron Burky
Phyllis Thomson
Pete Walker
Lisa Donner

Manitoba Justice

Robin Winters
Issie Frost

Manitoba Health

Ron Hikel
Linda Bakken
Sue Hicks
Marcia Thomson
Pat Hosang
Brenda Snider
Dale Brownlee
Sandra Fidirchuk
Scott Murray
Joan Bickford
Ulrich Wendt
Heather McLaren
Vivian Sandberg

Appendix C

Nursing Practice Council – Health Science Centre

DRAFT

Nursing Practice Council

Terms of Reference

Purpose

- To set direction for Nursing Clinical Practice, Education and Research at the Health Sciences Centre
- To provide a forum for the discussion of professional nursing issues and to facilitate communication between clinical programs
- To develop processes for monitoring and evaluating nursing standards and the quality of care and service provided
- To ensure consistency in application of policies and procedures as they relate to nursing practice
- To ensure that the clinical programs are addressing nursing standards and indicators in their Integrated Quality Systems (I.Q.S.) monitoring and reporting
- To collaborate in multidisciplinary quality of care, risk management and service improvement initiatives

Reporting Relationship

- Advisory to the Chief Nursing Officer
- Liaises with, and supported by, Quality Support Services and Nursing Quality Resources
- Liaises with program nursing practice committees

Membership

• Chief Nursing Officer	1
• Director of Patient Services	1
• One representative from Central Support Services (Systems)	1
• Chairperson of Education Advisory Committee	1
• Chairperson of Nursing Research Committee	1
• One representative from Nursing Quality Resources	1
• Chairpersons or delegate of each program practice committee	9
• One or more nursing representative(s) from each clinical program	9
• Other staff resource nurses or program representatives may be invited to attend at the call of the Chair	

Chairperson

- Chief Nursing Officers (X 6 months, then reviewed) then Co-Chaired by Staff Nurse and Manager

Meetings

- Minimum of 10 per annum
- Requests to have an item placed on the Agenda will be accompanied by background information and outline and sent to the Chairperson at least one week prior to the next scheduled meeting

DRAFT

Responsibilities and Functions

Professional Practice

- To define and monitor the Preferred Directions for Clinical Practice
- To maintain and advance nursing standards in all clinical programs
- To participate in inter disciplinary issues that affect nursing practice in multiple clinical programs
- To provide a forum for the resolution of nursing issues
- To approve policies and procedures as they relate to nursing practice

Education

- To monitor the implementation of the Preferred Directions for Nursing Education in collaboration with the Educational Advisory Committee
- To support an extensive and pro-active educational program designed to meet the needs of patients, families, staff and students
- To promote communication among decentralized and centralized educational services

Research

- To monitor the implementation of the Preferred Directions for Nursing Research in collaboration with the Research Steering Committee
- To recognize the contribution of nursing research towards advancing the scientific basis for nursing
- To communicate the research activities in the program
- To communicate evidence based research activities

Process

- Members are expected to represent their constituents on matters of concern to nurses
- Members shall represent their constituency for a maximum for two years
- New members to the Council will be appointed/elected in June of each year so that the new members will commence their term in September
- Minutes of meetings are to receive the widest possible circulation
- Agenda items are to be submitted to the Chair at least one week prior to next scheduled meeting
- Smaller working committees may be required for specific projects

Committees Reporting to Nursing Practice Council

- Nursing Research Committee
- Nursing Education Advisory Committee
- Nursing Policy and Procedure Committee
- Nursing IHIS Advisory Committee
- Nursing week Planning Committee
- Program Nursing Practice Committees
- Nursing Recruitment and Retention Committee
- Nursing News
- Patient's Behavior Management Committee

Appendix D

Report of Critical Incidents – Health Science Centre

CORPORATE POLICY & PROCEDURE MANUAL	SECTION 10. ADMINISTRATION	POLICY NUMBER 10.60.60
POLICY TITLE INCIDENT REPORTING AND MANAGEMENT	APPROVED BY EXECUTIVE TEAM	DATE 92/02/26 R2-00/08/17 R3 01/02/01
		PAGE 1 OF 4

1.0 PURPOSE:

1.1 To define an incident.

1.2 To prescribe the process for handling and reporting an incident.

2.0 DEFINITION:

2.1 Critical incident event:
A **critical incident event** is any incident which has/or could lead to:
- death or serious deterioration in the state of health of a patient or other individual on HSC premises, or could do so if the situation were to recur
- legal investigation/suit against the Centre or individuals associated with the Centre
- public enquiry
- government enquiry
- sensational media coverage
- insurance claim, theft or damage leaving an area unusable or requiring evacuation

2.2 Non-critical incident:
A non-critical incident is any occurrence associated with:

2.2.1 Injury or probable injury to any individual on HSC premises or occurring during performance of HSC business;

2.2.2 Fall or other accident on hospital premises, even with no apparent injury;

2.2.3 Deviation from legislation, hospital policies, procedures, standards and guidelines which could potentially cause a negative outcome; eg.
- Test or treatment done on wrong person
- Medication /therapeutic agent issues
- Breach of confidentiality policies:
  60.01.40 Confidentiality Policy – Personal Health Information
  60.01.50 Confidentiality Policy Governing the Protection of Corporate Information
  10.30.20 Conflict of Interest

2.2.4 Loss of or damage to the property of the HSC or of any individual on HSC premises, or occurring during performance of HSC business; eg.
- Loss of valuables or property
- A water leak which causes damage that impacts patient care, restricts normal business or causes injury

2.2.5 Financial loss or liability exposure of the HSC and/or staff; eg.
Equipment or supplies not available for patient care or departmental operation and

CORPORATE POLICY & PROCEDURE MANUAL	DATE 92/02/26 R2-00/08/17 R3 01/02/01	PAGE 2 OF 4	POLICY NUMBER 10.60.60

the unavailability was detrimental to patient outcomes or could have caused a serious negative outcome; or

2.2.6 Loss or damage to the reputation of the HSC or any other individual performing HSC business.

2.3 Individuals associated with HSC shall include all individuals who provide service to the Health Sciences Centre:

2.3.1 Within the framework of the employer - employee relationship;
2.3.2 Members of Medical Staff as defined by WRHA Hospital Medical Staff By-law;
2.3.3 Under the terms of any contract by which an individual provides service to the Health Science Centre;
2.3.4 as a student;
2.3.5 as a volunteer.

3.0 POLICY:

3.1 Central Support Services is responsible to manage the incident reporting system.

3.2 Subject to 3.3 any individual associated with the Health Sciences Centre who:
a) Discovers an incident, or
b) is involved in an incident, or
c) has witnessed an incident, or
d) has been advised that an incident has occurred
shall handle and report the incident as defined in the procedures.

3.3 Only one HSC incident report form is required for each incident event but all relevant reporting individuals including witnesses shall be identified on the report.

3.4 Staff shall not discuss any incident with or in the presence of patients, visitors, others outside the hospital or staff not involved in the incident, without the specific permission of their supervisor.

3.5 When the incident results in injury or illness an employee shall also complete and submit the Employee Work Related Illness and Injury Report, in accordance with Corporate Policy 40.110.30.

4.0 PROCEDURE:

4.1 The first HSC employee involved in/handling the incident shall:

4.1.1 Take or initiate immediate action within their scope of duties or responsibilities required to correct the situation;
4.1.2 Take or initiate other measures to reduce injury/risk/ loss as necessary in the circumstances;
4.1.3 Maintain the scene of the incident, except where necessary to provide care, for any incident when the consequences of the situation are serious or could be potentially serious (i.e. shall permit nothing at the scene to be changed, altered, moved, thrown

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out, cleaned up in any way until direction is received from immediate supervisor). Protection Services may be called for assistance in securing the site:

4.1.4 For every **critical incident event** and any non-critical incident as required immediately notify their immediate supervisor or delegate and other departments as necessary (eg. Biomedical Engineering, Department of Occupational and Environmental medicine (DOEM), Property Services etc.).

4.2 The person completing the incident report form shall:

4.2.1 Complete the incident report objectively without personal opinion or conjecture;

4.2.2 Verify content is complete and accurate;

4.2.3 Immediately forward the No Carbon Required (NCR) copy of Incident report to Central Support Services for entry into the incident report data base.

4.2.4 Forward the rest of the incident report to their immediate supervisor or delegate prior to end of shift on which incident occurred.

4.3 The immediate supervisor/or designate shall:

4.3.1 Take or initiate any additional remedial action within his/her scope of duties or responsibilities required to correct the situation;

4.3.2 Take or initiate other measures to reduce injury/risk/loss as necessary in the circumstances;

4.3.3 Take control of the scene of the incident in conjunction with Protection Services to maintain its integrity, except where necessary to provide care, for any incident when the consequences of the situation are serious or could be potentially serious (i.e. shall permit nothing at the scene to be changed, altered, moved, thrown out, cleaned up in any way) until they are satisfied that all required information has been obtained;

4.3.4 **Critical incident event**

4.3.4.1 Immediately notify Director or delegate and other department as required, e.g. Biomedical Engineering, DOEM, Property Services etc.

4.3.4.2 Route the incident report and any required supporting documentation to Director or delegate within 24 hours.
Note: a photocopy may be sent to any other affected departments or programs as needed within 24 hours.

4.3.4.3 Send incident report to CSS once completed.

4.3.5 Non-critical Incident event

4.3.5.1 Review and ensure the incident report is complete, accurate and signed

4.3.5.2 Route the incident report and any required supporting documentation to next level of management as needed within 7 working days.
Note: a photocopy may be sent to any other affected departments or programs as needed within 7 working days.

4.3.5.3 Send incident report to CSS once completed.

4.4 The Director /delegate shall:

4.4.1 For every **critical incident event** and any other incident as required immediately notify the Administrator on call and the Executive Team Member(s) appropriate to

CORPORATE POLICY & PROCEDURE MANUAL	DATE 92/02/26 R2-00/08/17 R3 01/02/01	PAGE 4 OF 4	POLICY NUMBER 10.60.60

the circumstance.

4.4.1.2 Route the incident report to their Executive team member with any other necessary documentation within 72 hours of the incident

4.4.1.3 Notify and route the incident report and other supporting documentation to the Medical Information Department when there is a serious or potentially serious consequence for the patient.

4.4.1.3 Route the incident report and supporting documentation to Director of General Accounting Finance when an insurance claim is made in relation to an incident.

4.4.2 For non-critical incident event reviewed by the Director :

4.4.2.1 Review and ensure the incident report is complete, accurate and sign

4.4.2.2 Route a copy of incident report and any required supporting documentation to next level of management and other affected programs/departments as necessary in the circumstances within 7 working days following receipt.

4.5 The Director/Department Head/Manager of other affected or notified departments shall:

4.5.1 Immediately notify the Director of Corporate Affairs, Administrator on Call and appropriate Executive Team Member(s) appropriate to the circumstance of every **critical incident event** and any other incident as warranted.

4.5.2 Route the incident report to Executive Team Member and other necessary documentation of any **critical incident event** within 72 hours of the incident.

4.5.3 Forward a copy of the follow-up or provide status report for any non-critical incident event to the Manager who initiated the incident report within 7 working days of that incident.

4.6 The supervisor responsible for Central Incident Reporting Process shall provide data entry support for HSC departments and distribute management reports.

Appendix D

Appendix E

Briefing Note on U.S. Whistleblowing Protections

The development of whistleblowing laws in the United States began in the early 1980s. Today nearly all of the states and the federal government have some form of whistleblower protection.

The underlying purpose of whistleblower protection laws is to allow employees to stop, report or testify about employer actions that are illegal, unhealthy or violate specific public policies.

Whistleblowing laws can apply to employees in either or both the public and the private sectors. Laws can be general in their application or to specific fields of activity. Depending upon whom one works for and in which state one is employed, the nature and scope of whistleblower protection is varied. In addition to explicit whistleblower protection laws, employees may also be protected under traditional tort or contract for damages resulting from retaliation for whistleblowing.

In the United States, there is an extensive "public interest" lobbying movement that promotes government accountability through a variety of mechanisms, such as freedom of information laws and whistleblower protection laws. The leading such organization seems to be "The Government Accountability Project" (GAP), which has led the public campaign for the Whistleblower Protection Act (WPA) which covers federal employees, the Military Whistleblower Protection Act (armed services) and the numerous statutes for private industry sectors, such as the nuclear industry, transportation fields and occupational health and safety.

The remainder of this briefing note will concentrate on the protection for federal employees within the U.S. government. The Civil Service Reform Act of 1978 (CSRA) marked the emergence of the whistleblower protection movement. The CSRA created three new organizations: the Office of Personnel Management (OPM), the Merit System Protection Board (MSPB), and the Office of the Special Counsel (OSC). The MSPB holds hearings and appeals of employee's grievances. The OSC, an external control agency, is charged with investigating whistleblower allegations of waste, fraud, and abuse, and complaints by federal employees claiming to have suffered reprisals for the lawful disclosure of information that they reasonably believed was evidence of unlawful behaviour, waste, mismanagement, abuse of authority, or a substantial and specific danger to public health or safety. The law protects whistleblowers from such negative personnel actions, as termination, demotion transfer and from negative inactions such as failure to promote.

Congressional hearings on the CSRA in the mid-eighties involved many witnesses claiming there was inadequate protection for whistleblowers and most of the blame was laid at the doorstep of the OSC. Special counsels, it was argued, had been lackadaisical in enforcing the Act. Calls to strengthen the law were based on the low ratio of cases in which the OSC ruled in favour of whistleblowers and by a survey that found 37 percent of employees would not blow the whistle for fear of reprisal.

Two comments might be made on these findings. First, Congress interpreted the rejection of the vast majority of whistleblower claims as a failing of the OSC rather than as evidence of possible misuse of the process. Second, it is probably the case that, no matter how strong the statutory protection, only a minority of people in any organization are likely to challenge organizational loyalty and to risk the social stigma that would follow.

The Whistleblower Protection act passed in 1989 strengthened the whistleblowing process in five ways:

1. It made the OSC more independent of the MSPB so that it would be an advocate for self-proclaimed whistleblowers, rather than a watchdog for the merit system.

2. It permitted whistleblowers the option of bypassing the OSC entirely and taking their complaints directly to the MSPB.

3. It lowered the standard of proof necessary to make out a case of protected whistleblowing. The employee must show that his or her disclosure of information was "a factor" (rather than the predominant or motivating factor) in the subsequent negative personnel action or inaction.

4. It provided that once an employee showed that the disclosure was a factor in the negative personnel action or inaction, the burden of proof shifted to the agency, which must provide that it would have taken the same personnel actions regardless of the disclosure.

5. It authorized lawyers' fees in the event that the whistleblower prevailed before the MSPB.

The 1989 amendments led to the reorganization of the OSC into an agency whose sole purpose is to protect whistleblowers rather than to protect the integrity of the civil service merit system. Further, the law was amended to remove almost completely the agency head from participation in the investigation. Each year there are proposals presented to both houses of Congress to widen the scope and to strengthen the protections provided to federal employees under the ***Whistleblower Protection Act*** of 1989.

In addition, new types of whistleblower protection workers in private industry are regularly being added. According to advocacy groups, like the National Whistleblower Center, the patchwork nature of the statutory protections has hindered aggressive litigation and enforcement of whistleblower protection provisions. Only employees in specific industries and certain types of conduct are protected. Each statute has its own filing provisions, its own statute of limitations and its own administrative or judicial remedies. Thus, each potential whistleblower case must be evaluated on the basis of who the employer is, what the disclosure concerns, and in which state the whistleblowing occurred.

In a recent paper, Tom Devine, Legal Director of the Government Accountability Project argued that the protection for whistleblower rights have been "largely symbolic and therefore counterproductive. Employees have risked retaliation thinking they had genuine protection, when in reality there was no realistic prospect they could maintain their careers." Reviewing the laws and cases over the preceding 23 years, Devine drafted a checklist of 21 requirements for effective whistleblowing laws:

1. no loopholes – protection should cover any disclosure that would be accepted in a legal forum as evidence of significant misconduct or would assist in carrying out legitimate law enforcement functions

2. realistic scope of subject matter – cover disclosures of any illegality, gross waste, mismanagement, abuse of authority, substantial and specific danger to public health and safety

3. includes a duty to disclose illegality – this provision switches disclosure from a personal initiative to a duty

4. right not to violate the law – can remove pressure on employee and may prevent the need for whistleblowing

5. protection for full scope of activity that leads to harassment – law should cover all scenarios that could have a "chilling effect" on the responsible exercise of free speech;

6. coverage for all employees performing public service functions – protection should extend to all parts of the "public sector" broadly defined and to private contractors delivering public services

7. coverage for confidential disclosure – there should be protected channels for those who choose to make anonymous disclosures

8. protection for all forms of harassment – necessary to ban both active and passive forms of reprisal, as well as recommendations for actions that constitute discrimination

9. anti-gag provision – a ban on gag orders to prevent prior restraint

10. prominent posting of rights – whistleblower rights, along with the duty to disclose illegality, must be posted prominently in any workplace.

11. a right to a jury trial – administrative boards have a poor track record of protecting whistleblowers and a jury represents the citizens that whistleblowers purport to be serving

12. option for alternative dispute resolution – use of an arbitrator selected by mutual consent allows the whistleblower access to a less costly, expedited process

13. modern burdens of proof – the standard flowing out of 1989 *Act*: there must be a preponderance of evidence that the protected conduct was a "contributing factor" to discriminatory action

14. realistic statute of limitations – most laws require action within 30 – 60 days, but it is more realistic to allow up to a year for a whistleblower to invoke their right to protection

15. full scope of consequences – if a whistleblower prevails, the relief must be comprehensive to cover all the direct, indirect, and future consequences of the reprisal

16. interim relief – to allow for the fact that appeals could drag on for years

17. attorney fees should be paid for all who substantially prevail

18. transference preference – in order to prevent repetitive reprisals, for those who prevail there must be an opportunity to transfer to obtain a fresh start

19. personal accountability for wrongdoers – to determine repetitive violations, it is indispensable that those responsible for whistleblower reprisal must be held accountable.

20. laws that are additive, not substitutive – ensure that new or strengthened laws do not cancel out pre-existing constitutions or common law rights

21. action against wrongdoing exposed whistleblowing disclosures – studies confirm that it is not fear of retaliation, but pessimism that nothing will be done that leads to silence. An effective law must channel disclosures into appropriate executive or legislative investigations and actions.

It should be noted that these 21 principles are written from the prospective of the whistleblower. They do not question the moral ambiguity of the activity. They do not discuss the responsibilities and accountabilities of the whistleblower. They also reflect the unique constitutional and legal context of the United States that has produced a strong "rights-orientation" and a litigious culture. In contrast, Canada has always represented a more deferential political culture. The principles of collective and individual ministerial responsibility have served to concentrate authority and power in the hands of the Prime Minister and Cabinet. Traditionally, the public service owed undivided loyalty to the currently serving prime minister and to the individual minister who leads their department. Canadian public servants are expected to be discrete in their public statements, relatively anonymous and neutral. In contrast, the American constitutional system of division of powers and checks and balances leads to divided loyalties for public servants (to the President, Congress, the public, etc.) and to more of a public role of advocacy and protection of the so-called "public interest."

Paul Thomas
February 5, 2001

Appendix F

Briefing Note on the United Kingdom's Public Interest Disclosure Act, 1998

The ***Public Interest Disclosure Act*** was passed by the U.K. Parliament in 1998 and came into force in January 1999. It amended the ***Employment Rights Act***, 1996 by introducing new rights not to suffer dismissal or detriment for making a protected disclosure. It applies to virtually all workers in the public and the private sector.

The ***Act*** aims to encourage problems to be resolved within the workplace, with public disclosures to be made only in limited circumstances. (Find more details)

The ***Act*** applies to virtually all employees in the public and the private sector, including to National Health Service (NHS) practitioners, such as physicians, dentists, pharmacists, etc.

Section 1 of the ***Act*** specifies the types of behaviour, disclosure of which be protected against reprisals (called "qualifying disclosures"):

- criminal offenses
- failure to comply with legal obligations
- miscarriage of justice
- health and safety risks
- environmental risks
- concealing information about any of the foregoing

Disclosures may be protected even if they are about matters which took place abroad.

Protection applies where a worker makes a disclosure:

- in good faith to his employer or to another responsible person;
- in the course of obtaining legal advice/note there are no conditions attached to protection where a worker makes a disclosure to a legal adviser;
- in certain cases, to a government minister; and
- to a person or body prescribed by the Secretary of State.

In all cases, protection applies provided that the worker acts in good faith, reasonably believes that the information falls within the potentially protected categories and is substantially true.

Protection is provided for workers who make "external" disclosures, that is other than to the employer, a legal adviser or a prescribed person. Significantly, a worker making external disclosures will only be protected if he/she has previously disclosed to the employer or a prescribed body, or has not done so because of reasonable belief of reprisal or the concealing/destruction of reprisal or the concealing/destruction of evidence. Whistleblowers must not act for personal gain.

Any terms in an agreement between a worker and his/her employer are void if they preclude or restrict whistleblowing (the so-called contractual "gagging" clauses).

Employees are not to be subject to detriment for making a protected disclosure. "Detriment" may include any action against an employee, for example, demotion, failure to give a promotion or training or withholding a pay increase. Contract employees can claim under this if their contracts are terminated. Because regular employees can claim unfair dismissal the right to complain of detriment does not apply to employees who are dismissed.

A tribunal is created to enforce the *Act*. In deciding whether the worker acted reasonably the tribunal will take into account all the circumstances, including particularly:

- the identity of the person to whom the disclosure is made;
- the seriousness of the matter;
- whether the problem is continuing;
- whether the disclosure is in breach of the employer's duties of confidentiality to any other person;
- any action the employer or the prescribed person might reasonably be expected to take as a result of a previous disclosure;
- whether the disclosure was made in accordance with any internal procedures approved by the employer.

Since the *Act* comes into force only in 1999, evidence on its impacts is difficult to locate.

In the case of the health field, the *Act* operates within the context of wider reforms to strengthen accountability of health providers to government and to the public. The Labour government of Tony Blair, elected in 1997, issued a white paper "The New NHS: Modern, Dependable (1997) which indicated that the government would "strengthen the existing system of professional self-regulation by ensuring they are open responsive and publicly accountable" (p. 97). This was followed by the announcement that for the first time hospital trusts would be held legally accountable for the quality of service they provide. Another document "A first class service: Quality in the New NHS" (1998) proposed a comprehensive, management-led system of clinical governance designed to set and monitor clinical standards. Self-regulation remains, but it must be modernized to ensure that it is:

> open to public scrutiny; responsive to changing clinical practice and changing service needs; and publicly accountable for professional standards set nationally and the action taken to maintain those standards (DOH, 1998, para. 3.44).

"Government," says the document, "will take responsibility for clarifying which treatments work best." This statement represents a fundamental shift, if it happens: the government is proposing to take ultimate responsibility for clinical standards. There is the question of whether the NHS can fulfill this responsibility through the proposed National Institute for Clinical Excellence (NICE) which would perform clinical evidence collection and appraisal functions. There is also the question of whether governments will regret taking in part at least the responsibility for clinical standards away from the professions because governments will become more direct targets for patient dissatisfaction with clinical decisions.

In 1999, the Blair Government issued another consultation paper, "Supporting doctors, protecting patients' (MHS, 1999) setting forth an array of proposals designed, first, to prevent problems and, second, to deal with deficiencies in performance. Among the key recommendations were:

- greater guidance and supervision to doctors in training

- appraisal of performance of doctors will become comprehensive and compulsory and will become part of the "revalidation" process operated by the General Medical Council;
- participation in clinical audits will become mandatory for both hospital doctors and GPs.

In addition to these preventative steps, the government proposes to deal with poor physician performance by abolishing existing disciplinary procedures and substituting a new integrated process involving NHS and the several professional bodies. In simple terms, there would be three steps for dealing with doctors with problems:

- serious clinical problems or mistakes would be referred immediately to the General Medical Council (regulatory body) whereas less serious doubts about clinical performance would be referred to an Assessment and Support Centre (see below);
- Assessment and Support Centers would be established to work with doctors to correct deficiencies in performance. Remedial actions could take a number of forms: return to practice, monitoring of practice, re-education followed by reassessment, referral back to the health authority as a serious and intractable problem and referral to the GMC
- the employer or health authority would accept responsibility for implementing findings of the Assessment and Support Centre, with provision for the doctor to appeal actions.

The consultation paper claims to propose a system which balances the interests of the profession, the regulatory bodies, the NHS and the public in a fair and flexible manner. Submissions on the paper closed in March, 2000 and what action, if any, has been taken on the proposal is unknown at this time.

Appendix F

Biliography

Websites by Reference Topic

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